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Connecticut Medicine

The Journal of the Connecticut State Medical Society

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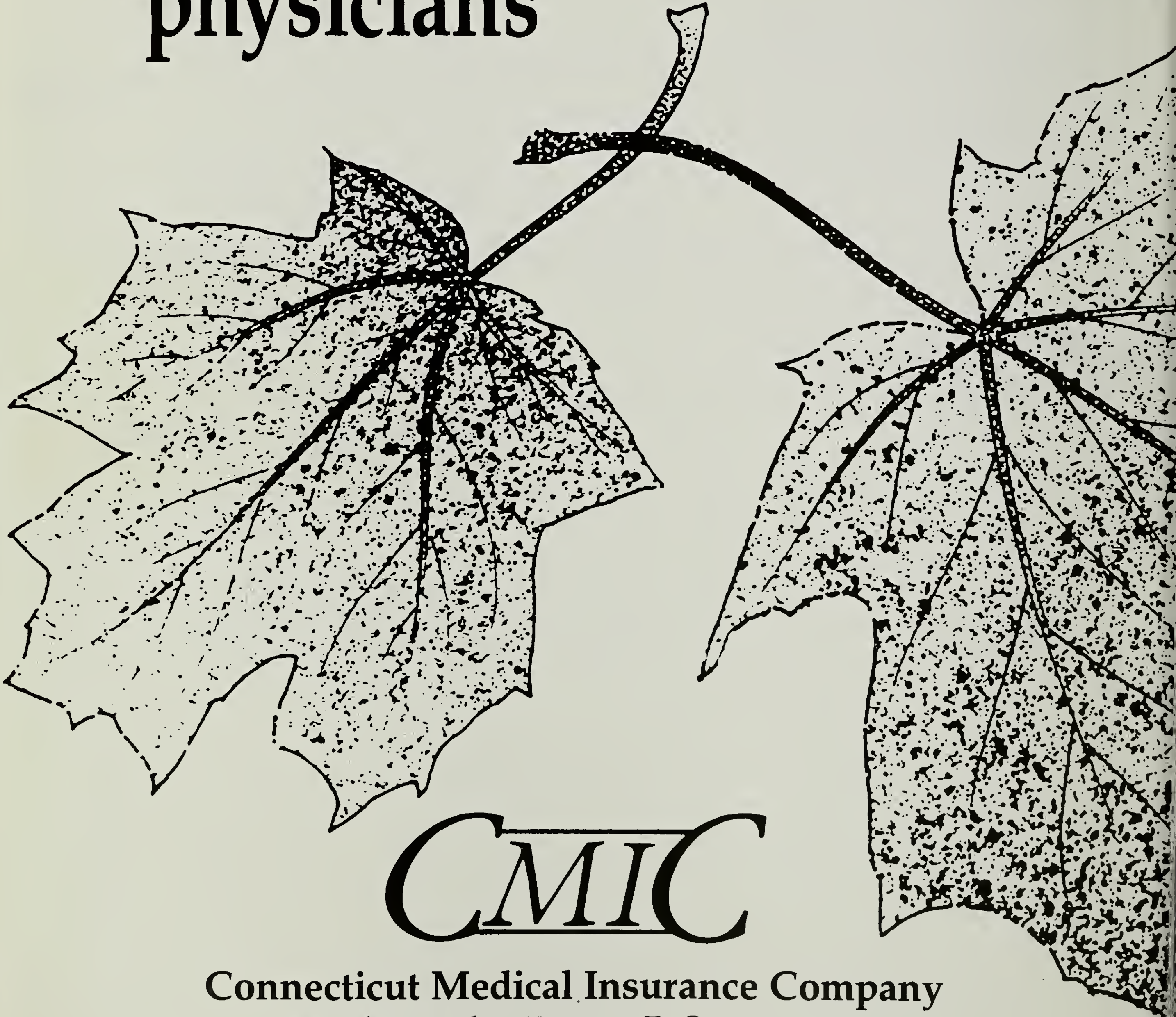

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Mammography in Connecticut:

Current Estimates of Capacity and Usage

DAVID I. GREGORIO, PH.D., M.S., STEPHEN KEGELES, PH.D.,
CHRISTINE PARKER, B.S., AND SUZETTE BENN, M.S.P.H.

ABSTRACT—All 124 registered mammography facilities in Connecticut were surveyed in 1988 to determine the availability, quality, and usage of mammography services. A total of 112 responses (90% return) were analyzed. By the measures considered here, capacity and quality of mammography in Connecticut is very good to excellent. Services are available in Connecticut in a wide array of locales, times, and settings. Since 1985, 95 new dedicated machines have been put into service. We estimate that current capacity may exceed 400,000 annual studies. Utilization is below current capacity; roughly 155,000 examinations were completed in 1988. Continued recognition of the procedure's effectiveness, particularly in screening women for evidence of early disease, can help reduce the burden of breast cancer.

Introduction

BREAST cancer is greatly feared by women. It is both a major source of premature mortality, as well as a disease associated with significant morbidity and disfigurement, often during the prime of life. In Connecticut this year, more than 2,000 cases of breast cancer will be diagnosed.[1] Estimates provided by Feldman et al[2] suggest that more than 14,000 Connecticut women are currently living with the disease.

Fortunately, breast tumors that are diagnosed early are both easier to treat and offer the greatest hope for cure.[3] The regular use of mammography has been shown to significantly reduce morbidity and mortality associated with the disease.[4-10]

Current screening guidelines promulgated by the American Cancer Society (ACS), the National Cancer Institute (NCI), and several national professional organizations advise women at age 40 who are without symptoms or other high risk factors to be screened for breast cancer using mammography and clinical breast examinations every one to two years (depending on their physician's discretion), and annually after age 50.[11] A *Year 2000* goal of the NCI is to increase to 80% the proportion of women aged 50 to 70 who receive annual physical breast exams coupled with mammography.[12] A 1991 objective of Connecticut's Cancer Control Program calls for the percentage of women receiving annual physical breast exams and mammograms to increase from its current level of 25% to 40%.

While considerably fewer Connecticut women than desired currently utilize mammography services and several significant gaps of coverage have been noted,[13] use of mammography in the state has increased in recent years. A 1988 survey by the Connecticut Department of Health Services found that 39% of the women questioned had had a mammogram over the preceding two years.[14] Recent legislation requiring health insurers to provide coverage for costs of mammography examinations is expected to reduce what many observers believe is a significant barrier to greater utilization of the procedure, ie, high cost.

This paper summarizes the results of a recent survey of mammography facilities in Connecticut. The data characterize the current capacity and utilization of equipment. Options for increasing utilization of this technology by women, and enhancing the quality of services offered them are also discussed.

Methods

The operation of mammography equipment in Connecticut is monitored through mandatory registration by facilities with the state's Radiation Control Division of its Department of Environmental Protection. At the time of survey, 124 facilities were registered, with an additional 15 nonregistered facilities in operation. We are uncertain whether the latter are satellites of other

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Reprint requests to Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington. (David I. Gregorio, Ph.D., M.S.)

registered facilities, or whether they remain in noncompliance with state regulations.

As part of Connecticut's Cancer Control Demonstration Project (NIH/NCI Grant #CA 43522-01), all 124 registered mammography facilities were contacted by Department of Health Services personnel during January 1988 and asked to complete a brief survey regarding the availability (location, hours of operation, etc.), quality (type of equipment, qualifications of personnel, scope of services, etc.) and usage (number of examinations) of mammography services over the preceding year. Both screening and diagnostic studies were addressed.

Nonrespondents to the initial inquiry were recontacted by mail in March 1988 and by telephone follow-up in June of the same year. Responses were received from 112 facilities (90% of registered units). No differences were detected between facilities which responded to the follow-up, as opposed to initial, contacts.

Findings

Overall, by the measures considered here, the capacity and quality of mammography in Connecticut is very good to excellent. Mammography has been available to Connecticut residents since 1941, although most services are of more recent origin. As shown in Table 1, roughly one half of facilities that responded to the survey (53 of 109; 49%) have operated less than five years, with 10 of those coming on-line since 1987. Only 45 facilities, or about one third of the state's current capacity, were reported to have been operating 10 years ago.

At the time that responses were received, only three mammography facilities in Connecticut had sought accreditation of their service by the American Radiology Society. (Note: Follow-up reports indicate that 15 Connecticut facilities (12%) have sought accreditation since that time.) Cost ($500 per unit annual registration fee) and testing requirements may account for the relatively low degree of participation by facilities in this program.

Nearly all mammography facilities (104 of 112) reported use of only dedicated equipment for mammographic examinations. Telephone rechecks during January 1989 of the eight facilities using nondedicated equipment noted that 5 facilities no longer utilize such equipment, while use of nondedicated machines by the remaining 3 facilities continues with substantially reduced hours of operation.

Conservatively assuming that each registered facility operates a single dedicated machine for a maximum of 35 hours each week, and that 30-45 minutes are required to complete a single study, the current capacity for mammography in Connecticut may be as great as 400,000 annual mammograms. Actual capacity may exceed that estimate, however, based on the number of mammography *units* installed here, equipment specifications, and standards of practice.

Access of women to services within Connecticut similarly is good. Mammography is offered at 27 of the state's 36 acute care hospitals, accounting for nearly one quarter of all registered equipment operated here. Facilities in private radiology offices account for an additional one half of the mammography equipment, with the remainder (29 facilities) located in such settings as an HMO, private and group medical offices, and free-standing mammography clinics. Two mobile screening vans currently offer coverage to the North Central (Greater Hartford) and South Central (Greater New Haven) regions of the state. Nearly all facilities (95%) reported that they are accessible by public transportation.

Table 1
Selected Characteristics of Registered Mammography Facilities, Connecticut, January 1988.

		Number	*Percentage*
YEARS in operation			
< 2 years (1987-88)		10	9%
3 - 5 years (1984-86)		43	39%
6 - 10 years (1979-83)		11	10%
11 - 15 years (1974-78)		24	22%
>15 years (pre-1974)		21	19%
ACR ACCREDITED facility		3	3%
EQUIPMENT in use			
Nondedicated		8	7%
Dedicated		104	93%
SETTING of facility			
Hospital radiology department		27	24%
Private radiology practice		56	50%
Other†		29	26%
LOCATION of facility			
Southwestern	(HSA1)	27	22%
South Central	(HSA2)	27	22%
Eastern	(HSA3)	14	11%
North Central	(HSA4)	38	31%
Northwestern	(HSA5)	18	14%
ACCESS through public transportation		106	95%
OPERATING schedule			
Full-time hours (35+hrs/week)		96	86%
Weeknight hours		19	17%
Weekend hours		27	24%
TYPE of examination			
4-view study		28	25%
2-view study		80	71%
Other		4	4%

† Other locations include private medical offices (n=6), group medical offices (6), HMO (1), free-standing mammography clinic (10), and miscellaneous (6).

The median waiting time by women for an appointment was estimated as being within two days. No fewer than five in six facilities reported that waiting time for appointments typically was less than one week.

Only 14% of facilities reported operating less than a full-time schedule (ie, less than 35 hours each week). On the other hand, availability of services outside of regular business hours is limited. Only 17% and 25% of facilities indicated that they operate during evening or weekend hours, respectively.

Regarding the nature of examinations offered by mammography facilities, one quarter of responding facilities indicated that four-view per breast studies were routinely completed. The majority of respondents (80 of 112; 71%) reported performing two-view per breast examinations.

Incomplete information is available about current use of equipment. Of the 99 facilities (88% of respondents) that reported on utilization, a total of 155,947 mammograms were recorded. On average, each of those facilities reported 838 screening mammograms and 687 diagnostic studies during that time period (See Table 2).

All facilities responding to the survey indicated that the procedure for mammography is explained to patients

Table 2
Mean Volume of Mammography Services, Connecticut, January 1988, (n=99).

	Mean Volume Per Facility			
Type of Examination	*Total*	*Hospital*	*Private Offices*	*Other†*
Screening mammogram	838	847	909	720
Diagnostic mammogram	687	811	717	471
All mammograms	1,525	1,658	1,626	1,191

†Other locations include private medical offices, group medical offices, HMO, and free-standing mammography clinics.

at the time studies are done, and nearly all include individual health histories as part of the examination (See Table 3). Regarding other services that facilities offer women in conjunction with mammograms, we observed several limitations. Most notably, other modalities for early breast cancer detection are underemphasized by many who responded to the survey. Roughly one quarter of respondents indicated that instructional pamphlets on breast self-examination (BSE) are not available to patients in their offices, while fewer than one half (42%) of facilities provide instructional tapes or hands-on models for training women in the techniques of self-examination. Only a minority of facilities (40%) provide physical breast examinations as part of their cancer screening service. Advice regarding the importance of routine physical examinations or consultation on breast cancer risk factors is also uncommon (40% and 38%, respectively responded that such service is offered). Interestingly, nine of 10 respondents (88%) indicated that patients are advised about recommended screening intervals at the time of examination, but only one in three facilities noted that they systematically notify women that they are due for repeat screening.

Discussion

The capacity, quality, and usage of mammography has expanded greatly in recent years. Most facilities in Connecticut have been in operation fewer than 10 years, and the majority of women who have obtained mammograms have done so over the past 24 months. Our evaluation of mammography facilities operating in this state revealed a service of high quality utilizing dedicated equipment, which is readily available and accessible to women. Continued recognition of the procedure's effectiveness along with continuing efforts to reduce cost and improve access will help to assure that screening mammography will become an integral part of women's health care. Health care practitioners, in particular, can play an important role in assuring that asymptomatic women are referred for periodic screening.[13]

Mammography facilities, for their part, can help to assure that asymptomatic women are adequately screened for the disease. Efforts to encouraged combined methods for breast cancer screening—mammography *in conjunction* with periodic physical breast examinations and regular BSE—can help reduce the burden of this disease in our population. Attention to expanded hours of services during evenings and weekends may also be warranted.

Table 3
Breast Cancer Screening Services Offered, Connecticut, January 1988.

	Type Of Facility			
Services Offered	*Total*	*Hospitals*	*Private Offices*	*Other†*
Explain mammography procedures	100%	100%	100%	100%
Take individual health history	96%	93%	96%	100%
Advise on recommended screening interval	88%	85%	93%	83%
Offer BSE instructional pamphlets	78%	70%	82%	79%
Follow-up on suspicious findings	52%	46%	50%	61%
Offer BSE instructional videotapes	42%	37%	36%	59%
Provide models for hands-on BSE training	42%	37%	36%	59%
Advise on need for physical breast exams	40%	22%	49%	41%
Perform physical breast exams	40%	37%	38%	48%
Consultation on breast cancer risk factors	38%	18%	42%	48%
Notify women for repeat screening	32%	15%	29%	55%

†Other locations include private medical offices (n=6), group medical offices (6), HMO (1), free-standing mammography clinic (10), and miscellaneous (6).

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Encouraging Screening Mammograms

Results of the 1988 Connecticut Breast Cancer Detection Awareness Campaign

DAVID I. GREGORIO, PH.D., M.S., STEPHEN KEGELES, PH.D.,
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ABSTRACT—Connecticut's first Breast Cancer Detection Awareness Campaign during April 1988 offered low-cost screening mammograms ($50) to women over age 34 who had not been previously examined. Following a brief mass media campaign, some 2,500 inquiries about the program were received over a seven-day period, resulting in 1,243 examinations and the detection of eight breast cancers. Program participants cited an enhanced awareness that a baseline examination was due, and knowledge about the availability of low-cost services as reasons for obtaining a screening mammogram. Their reasons for not having been previously screened included not having been advised by physicians to have such an examination (28%); high cost(37%); and failure to recognize the importance of periodic screening (21%). By contrast, relatively few women expressed concern about the test procedure (12%), or fear of finding cancer (9%) as reasons for not being screened previously. These findings underscore the benefit of cancer control efforts to reduce access and information barriers to regular use of mammography by women.

MAMMOGRAPHY, by virtue of its effectiveness in identifying nonpalpable breast tumors,[1] has been shown to reduce morbidity and mortality associated with the disease.[2-5] Given the burden of breast cancer in our population, it is important that mammography becomes an integral part of women's health care. Guidelines promulgated by the American Cancer Society (ACS), National Cancer Institute (NCI), the American Medical Association (AMA), and several national professional organizations (eg, the American College of Radiology, and the like) presently advocate a multimodality approach to breast cancer screening.[6] Women at the age of 40 who are without symptoms or other high-risk factors for breast cancer are advised to obtain a screening mammogram along with clinical breast examinations every one to two years (depending on the discretion of the physician). At age 50, it is recommended that such examinations occur every year.

A *Year 2000* goal of the NCI is to increase to 80% the proportion of women aged 50-70 who have an annual physical breast examination coupled with mammography.[7] A 1991 Connecticut Cancer Control Program Objective calls for the percentage of women receiving annual physician breast examinations and mammography to increase from 25% to 40%. Considerably fewer now utilize mammography regularly.[8-10]

In April 1988 the Connecticut Division of the ACS, in cooperation with the Connecticut Hospital Association (CHA), the Connecticut Radiological Society (CRS), the Connecticut Department of Health Services (CDHS), and the Yale Comprehensive Cancer Center (YCCC), conducted the first Breast Cancer Detection Awareness (BCDA) Campaign for state residents. As one aspect of that effort, a mass communication campaign was conducted to educate women about the importance, and means, of early breast cancer detection. At the same time women over the age of 34 who had not been previously screened were offered low-cost examinations ($50) at any one of 88 mammography sites that consented to participate in the project (71% of facilities contacted).

This paper examines the effect of the 1988 effort with particular attention to the motives given by participants for obtaining a mammogram at that time, as well as their reason for not having been screened previously.

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The 1988 Connecticut Breast Cancer Detection Awareness Campaign

Mammography screening of women was scheduled for 9 May - 30 June 1988, following a 30-day general information campaign using news releases and TV and radio public service announcements (PSAs). Interested persons were advised to call a special toll-free number to determine their eligibility for the program and to obtain information on available screening services. The toll-free hotline was operated by American Cancer Society volunteers from 25-29 April 1988, under the training and supervision of ACS and YCCC personnel. Callers who had other cancer questions were referred to the Cancer Information Service (1-800-4-CANCER).

Women were eligible for low-cost mammography screening if they had no prior breast cancer history, were not previously examined, were at least 35 years of age, and were neither pregnant nor nursing a baby. Eligible callers were sent a letter about the program, along with ACS brochures on mammography and breast health, and a list of participating mammography facilities within the state. A coupon offering a $50 mammogram before 3 June 1988 was included along with a request that a brief medical history form and consent form be completed by individuals. Women were asked to call the most convenient participating facility and arrange an appointment between 2 May and 13 May 1988.

At random, approximately 800 callers also received a questionnaire to be used in evaluating the low-cost screening program. Questionnaires inquired into the demographic backgrounds of women (eg, age, place of residence, education and income level, marital status, and the like), as well as why they were having a mammogram at this time, why they had not sought a mammogram previously, and how they learned about the screening program.

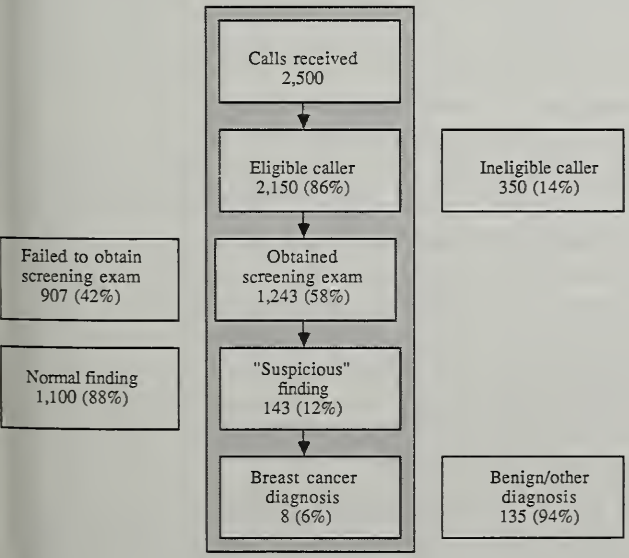

Figure 1
Response to the BCDA Campaign, Connecticut, April 1988.

Some 2,500 calls were received through the hotline during the subject enrollment period (See Figure 1). Of these, 86% (n=2,150) were determined to be eligible for low-cost examinations, with the remainder excluded primarily because of having had previous mammograms. A total of 1,243 women (58% of eligible callers) went on to obtain low-cost mammograms during the project period. Roughly one in nine examinations yielded suspicious findings that required follow-up. Of these, eight women were diagnosed as having cancer and have been treated for their disease.

Four hundred forty-six questionnaires were returned by women at the time of screening (56% of the number distributed) and are analyzed here. While an unspecified number of other screening subjects may have declined to return questionnaires at the time of their appointments, we believe our respondents are representative, in large part, of all women who participated in the 1988 campaign.

Findings

Overall, women who obtained screening mammograms as a consequence of the 1988 BCDA campaign tended to be young, white, married, well educated, and from middle to upper-income households (See Table 1). The average age of women who received first-time mammograms was 50.5 years, with roughly two thirds of participants being under the age of 65. Fewer than one in 16 participants had not obtained a high school diploma, and approximately two thirds of women (64%) had at least some college education. Nearly one half of subjects reported annual household incomes greater than $35,000.

Table 1
Selected characteristics of BCDA campaign participants, Connecticut 1988

1.	Mean Age	50.5 years
2.	Racial/ethnic background	
	White	96%
	Nonwhite	4%
	Spanish origin of either race	1%
3.	Highest grade of school achieved	
	Less than high school graduate	6%
	High school graduate	30%
	Some college	47%
	Post college education	17%
4.	Estimated annual household income	
	Less than $20,000	25%
	$20,000 - $34,999	29%
	$35,000 - $49,999	23%
	More than $50,000	24%
5.	Marital status	
	Married	76%
	Divorced/separated	12%
	Widowed	8%
	Never married	4%
6.	Place of residence	
	HSA 1 (Southwestern region)	19%
	HSA 2 (South Central region)	6%
	HSA 3 (Eastern region)	19%
	HSA 4 (North Central region)	39%
	HSA 5 (Northwestern region)	16%
7.	Family history of breast cancer	22%

A disproportionate number of respondents resided within the North Central region of the state (ie, Greater Hartford), whereas the proportion of women from the South Central area (Greater New Haven) was considerably below their proportion in the general population. Reasons for such discrepancies are unclear. Approximately one in five of women noted a family history of breast cancer.

Program participants were divided depending on whether they learned about the offer for low-cost mammograms through newspaper notices/articles (33%), radio PSAs (29%), or other miscellaneous sources (37%) (See Table 2).

Table 2

Source of information on availability of low-cost screening

Source	*Percentage*
TV	8%
Radio	29%
Newspapers	33%
American Cancer Society	10%
Other	19%

The reasons given by participants for obtaining mammograms during the 1988 BCDA campaign are reported in Table 3. Most respondents (44%) cited a belief that "it's time for me to have one," while an additional 16% noted a recent physician's recommendation as having influenced their decision. Roughly one quarter of women acknowledged that the availability of low-cost services was critical to their decision.

Table 3

Why are you having a mammogram at this time?

	#	%
It's time for me to have one	196	44
Because of the reduced cost ($50) program	119	27
My doctor told me to have one	71	16
I have breast cancer in my family	18	4
Other reasons	38	9
No reason given	4	—
Total	446	100

A second question, "Why is this your first mammogram?" may be interpreted as asking for reasons for not having had a previous examination. Significant numbers of women gave one of three reasons. (See Table 4): the failure of their physician to advise them to have such an exam (39%); the customary high-cost of screening (37%); and the belief that mammograms were not important for them (21%). By contrast, relatively few women expressed concern about either the testing procedure (eg, fear of radiation or pain) (12%) or fear of finding cancer as reasons for not being screened previously. Apparently issues of access (eg, cost barriers) and information (ie, the importance and appropriateness of periodic screening) were most influential in women's judgments, whereas beliefs about the procedure were relatively unimportant.

Table 4

Why is this your first mammogram?

	#	%
My doctor never told me to have one	169	39%
It cost too much	163	37%
I didn't think it was important	92	21%
Concern about the examination (x-rays, pain)	52	12%
Fear of finding cancer	39	9%
Miscellaneous other reasons	157	35%
No reasons given	10	—
Total responses	672*	—
Total respondents	436	†

* Responses exceed the number of respondents because women were able to identify more than one factor contributing to their behavior.

† Percentages reflect the proportion of 436 respondents who cited a specific reason for not having had a prior mammogram. Total exceeds 100% because women were able to identify more than one factor contributing to their behavior.

Discussion

Although a sizable (and expanding) group of women have regular mammograms, most women do not. The 1988 BCDA campaign offered first-time screening mammogram examinations to Connecticut women through a mass communication effort that stressed the importance of periodic screening and the limited availability of low-cost services. A total of 1,243 examinations were completed, yielding eight cancers.

Ongoing community-based public information campaigns such as the BCDA campaign can be important compliments to the efforts of health-care givers to inform women of their need for periodic breast examinations. Continued acceptance of the procedure's effectiveness by both the public and the health-care community will help assure that periodic screening becomes an integral part of women's health care. Recent efforts by national service and professional organizations (eg, ACS, AMA, and the like) to advance a consensus statement on recommendations for periodic screening should help clarify its appropriate use in the minds of women as well as for those providing their care.

Our experience in Connecticut was similar to that of other population-based programs across the country.[10] Current users tend to be women who are highly committed to breast cancer prevention as well as general health promotion.[11] Obstacles to its regular use of screening mammography include misconceptions by women that they do not require periodic examination; the failure of physicians to advise women about the importance of routine mammography; cost and access barriers to its use; women's fear of detecting cancer; and concern about the procedure's safety.[12-13]

Programs such as these underscore the utility of reducing access and information barriers for women to the regular use of mammography. Information about the importance of mammography and the availability of low-costs services was relevant in bringing roughly three of every four participants into the program.

Moreover, the 1988 BCDA campaign reflects the importance for future initiatives to tailor activities in order to reach women within high-risk population groups. Nonwhites, the elderly and the poor tend to be under represented among women who obtained examinations through such initiatives. Special action should be taken in all future programs to reach those targeted groups.

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Medicine as a Career

As the medical practice environment has changed, reports of disillusionment within the profession have increased and medical school enrollment applications have declined. The 1990 survey explored physicians' feelings about medicine generally and their own personal specialties in particular.

Advice to Students

As one measure of how physicians feel about their chosen profession, respondents were asked whether they would recommend medicine as a career. A majority said they would, but a significant minority said they would not.

If a high school or college student asked for your advice about becoming a physician, would you recommend medicine as a career choice, or not?

Physician Opinion 1990

Yes	58%
No	38
Unsure	5

Responses to this question are almost identical to physician reactions to a similar question one year earlier. Sixty percent of respondents to the 1989 survey said they, themselves, would definitely or probably go to medical school if they had the choice again, and 39% said they definitely or probably would not do so.

In support of the suggestion that the changing environment has increased disillusionment among practicing physicians, physicians 35 years of age or younger were more likely than their over-35 colleagues to say they would recommend medicine, 68% versus 55%. Similarly, women physicians (68%) were more likely to recommend medicine as a career than were men (56%).

In what could be interpreted as an encouraging note for the profession's future, 71% of teaching physicians said they would recommend medicine as a career. The proportion responding affirmatively was 64% among hospital-based physicians, 60% among group practice physicians and those in other types of employment. MDs in solo practice were evenly divided on this item: 48% said "yes" and 48% said "no."

Among the specialties, pediatricians were the least negative toward the profession on this measure: 27% said they would not recommend medicine, while 62% said they would and 11% expressed uncertainty.

—AMA Surveys of Physician and Public Opinion on Health Care Issues, 1990.

Women's Use of Mammographic Screening: The Role of Information, Cues, and Reinforcement

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ABSTRACT—Questionnaires were distributed to 359 women who had mammograms during the previous six months. Data were obtained on: 1) demographic variables; 2) perception of risk and sources of knowledge about breast cancer and mammography; 3) cues or events which initiated action to obtain a mammogram; and 4) behaviors or events which may reinforce the use of the procedure. A major goal of the research was to obtain information on factors hypothesized to effect women's use of mammography for the detection of breast cancer. High education and income levels, characteristic of women using screening procedures, were found in this sample. Availability of information and a realistic perception of risk were not sufficient motivators to obtain a mammogram. The recommendation of a health professional was reported to be the single most important motivating factor by 71% of the sample. Following the procedure, relief of anxiety, and verbal reinforcement by health professionals, friends, or relatives were reported. These results suggest that the most important cue for many women to obtain a mammogram is recommendation of a health professional. The role of reinforcement in repeating the behavior requires further clarification.

Introduction

THE role of the consumer in health care has increased dramatically in the past 10 years. Efforts in health promotion, emphasizing self-responsibility, reflect this trend focusing on the education and motivation of individuals and groups toward health promoting behaviors. Increasingly, it is becoming an expected role of the consumer to be informed and to act as a partner with the health professional in obtaining necessary health care.[1,2] The role of women as consumers in obtaining mammograms has not been fully addressed.

Women have been slow to accept and utilize the technology currently available to them for the early detection of breast cancer. The breast is the major site for developing cancer in women with 142,000 new cases anticipated for 1989, and the second leading site for cancer deaths in women.[3] About one in every 10 women in the United States will develop breast cancer during her lifetime. With mammography, utilizing low-dose x-rays, malignant tumors can be detected at very early stages of development greatly increasing the likelihood of cure. The American Cancer Society recommends a baseline mammogram for women ages 30-39, a biannual mammogram for women 40-49, and annual mammograms for women over age 50. With its use, tumors can be identified as early as three years before they can be palpated by the physician or by the patient during self-examination. Studies have demonstrated the significant benefits of the procedure in reducing mortality for women over 40 years of age.[5] However, less than 25 percent of women over the age of fifty utilize mammography for the detection of breast cancer.[6] The health behavior of some women is a major risk factor in early diagnosis. Explaining and changing this behavior would reduce the number of deaths from breast cancer through early detection.

Preventive Health Behavior Models and Mammography

Having a mammogram is preventive health behavior, that is an "activity undertaken by a person who believes herself to be healthy for the purpose of preventing disease or detecting disease in an asymptomatic stage."[7] Factors generally associated with preventive health behavior have been identified and explanatory models developed.

The Health Belief Model has been used to predict a variety of professionally recommended preventive activities including screenings for tuberculosis, cancer, and heart disease.[8,9,10] According to this model, health decision-making is conceived as a process in which the individual moves through a series of stages or phases. Decisions made at any one of these stages may increase or decrease the probability of further behavior. The three major components of the model include:

1) perceived vulnerability or susceptibility to a disease, and perception of the severity of the consequences of the condition;

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2) beliefs about the value and effectiveness of diagnosis;
3) an instigating event, a cue to action which actually sets the process of preventive health behavior in motion.

Previous studies have focused primarily on the first two components. These studies have generally supported the presence of a perceived vulnerability to breast cancer among women who obtain mammograms, and a perception of the benefits of the procedure.[11,12] Other studies have focused on barriers to obtaining mammograms which included a fear of pain, anxiety about discovering cancer, and lack of conviction of the efficacy of the procedure.[13,14,15]

A second model developed to explain preventive health behavior, the Instrumental Conditioning Model, suggests that the success and continuation of a new health-promoting behavior depends on the normal availability of "cues" and "reinforcers" for the behavior.[16,17] Few cues which result in a woman obtaining a mammogram have been identified. A "reinforcer" may be any event which rewards or reinforces a woman's decision to have a mammogram. To some extent, health professionals may provide such cues and reinforcers by recommending mammography, and then providing verbal support for the action taken. However, these cues and reinforcers are dependent on the frequency of contact with health professionals, and the degree of respect and liking for them.

It appears likely that the practice of healthy behavior requires both cues and reinforcers for that behavior; to the extent that the behavior has few cues or goes unreinforced, it is unlikely that women still will participate in screening activities. Identifying cues which motivate some women to obtain mammograms, and events which reinforce their decision, is essential to increase the use of mammography among women in the age groups at risk.

This research addressed three questions:

1) A "cue" may be any event which motivates people to obtain a mammography examination. What kinds of cues are more or less likely to be accepted and result in women obtaining mammograms?
2) What is the role of information and perception of risk?
3) Are there rewards or "reinforcing events" which are likely to increase use of the procedure?

Methods

A survey questionnaire was developed to obtain current data from women on factors hypothesized to affect their use of mammography for detection of breast cancer. This instrument focused on five dimensions:

1) *Demographic data* including age, marital status, education, income, and ethnicity
2) *Perception of risk,* and source of knowledge about breast cancer and mammography
3) *Cues or events* which initiate action to obtain a mammogram including physical symptoms, physician recommendation, experience of family member or friend
4) Behaviors or events which may *reinforce* or reward the use of mammography including relief of anxiety, support of health professionals, support of family and friends
5) The *cost* of the procedure, current reimbursement policies and availability of insurance coverage

Sample

The participants included 359 women who had obtained mammograms during a three-month period at a local community hospital or at a local free-standing mammography center separated geographically from the hospital. The mean age of the study group was 51 years. Previous studies of women using health screening procedures suggest high levels of education and income.[18] Similarly, high education and income levels were found in this sample. (Table I) Fifty-seven percent of the women had attended college and 43% had annual family incomes exceeding $40,000.00. These women were frequent users of the health-care system with 97% having visited a physician within the past year.

Table I
Sample Characteristics

Mean Age	51 years
Mean Years of Education	13 years
Mean Income Level	$41,000.00
Ethnicity	97% Caucasian

Results

Information and Perception of Risk

Various models of health promotion suggest that perceiving oneself at risk, and having information available on health promoting behaviors is likely to increase the use of preventive activities. In the study group, 67% of the women correctly estimated the one in 10 risk of a woman developing breast cancer within her lifetime. Only 4% *underestimated* the risk, and 27% *overestimated* their risk. These results suggest that this group of women perceived themselves to be at moderate to high risk for breast cancer. In addition, 23% of the women reported breast cancer in at least one family member, perhaps promoting a heightened sense of risk in the study group.

Women had obtained information on breast cancer and mammography from a variety of sources. (Table II) The most frequently cited sources were pamphlets (generally available in their physicians' office) and magazines. Only 6% of the women indicated that they had not obtained any infromation on breast cancer or mammography.

Cues or Events Leading to a Mammogram

The role of several cues or events which might initiate action to obtain a mammogram were investigated. These

Table II

Sources of Information

Source	*No.*	%
Pamphlets	210	58.5
Magazines	190	52.9
Television	134	37.3
Newspapers	134	37.3
None	20	5.6

included: 1) recommendation of a health professional, friend, or relative; 2) discovery of symptoms; 3) concern or anxiety about cancer; and 4) information from the media (Table III). Seventy-one percent of the women indicated that, for them, the most important reason for having a mammogram was the recommendation of their physician. The recommendation of a friend or relative was important for only 2.5% of the sample. A general concern about cancer was the motivating factor for 12% of the women. Although most women (94%) reported obtaining information from a variety of sources, this information was not reported to be significant in motivating them to obtain a mammogram.

Table III

Cues for Obtaining Mammogram

Cue	*No.*	%
M.D. Suggested	255	71.4
Worried About Cancer	44	12.3
Discovered Symptoms	20	5.6
Friend/Relative Suggested	9	2.5
Television Program	4	1.1
Magazine Article	1	.3

Reinforcing Events

In some models of preventive health behavior, the action is more likely to be repeated if the person is rewarded or reinforced for obtaining a screening procedure. The role of reinforcement in mammography is particularly important since it is recommended annually for women over 50 years of age. Reinforcing events which were investigated included reduction of anxiety and verbal support.

The use of screening procedures may increase anxiety, and, therefore, potentially reduce continued utilization. Relief or reduction in anxiety after the procedure was reported by 50% of the women, while no change in feelings was reported by 42%. Only 8% reported increased anxiety (Table IV).

Table IV

Feelings Reported Following Mammogram

Feeling	*No.*	%
Relief	178	50
No Change	150	42.1
Increased Anxiety	28	7.9

When asked if anyone made them "feel good" about having had a mammogram, 62% reported support from at least one source. Among those women reporting support, the most frequently cited source was the health professional (37%), while 18% reported support from a friend or relative (Table V).

Discussion

The results of this descriptive research suggest several factors which may have a significant affect on women's use of mammography for the detection of breast cancer, including: 1) the role of information about breast cancer and mammography; 2) cues which result in a mammogram; and 3) reinforcing events which may lead to repeat mammograms.

Some knowledge of breast cancer and the role of mammography was reported by 94% of the sample. However, the availability of information and a realistic perception of risk were not reported to be primary reasons for actually obtaining a mammogram. It appears that the information presently available to women is not sufficient by itself to motivate them to obtain a mammogram. Similarly, media events provided awareness, but were not considered a primary motivating factor for 99% of the women. Concern about cancer, and discovery of symptoms was the primary motivating factor reported by 12% of the women, and it is likely that these concerns interacted with available information to serve as a cue for the behavior.

In the study group, the recommendation of a health professional was reported to be the single most important factor in motivating a woman to obtain a mammogram. In 1984 an American Cancer Society survey of 1,035 primary care physicians showed 68% agreed with the Society's guidelines for breast cancer detection in asymptomatic women, but only 11% followed these recommendations.[19] In a similar survey in 1989, 37% of physicians reported following these guidelines.[20] If the physician is the key decision maker for this screening procedure, and his or her recommendation the primary motivator for women, then it is important to focus promotion efforts on the health-care provider, as well as on the women. In this sample, women were frequent users of the health-care system with 97% having at least one visit to a physician within the past year. For these women, the physician served as a primary motivator through recommendations and supply of informative pamphlets, but it is likely that women who are not frequent users of the health-care system lack access to these "cues" which motivate health promoting behavior. Studies demonstrate that women who are older, uninsured, or lower in socioeconomic status are at increased risk for not receiving preventive care. Screening mammography remains markedly underused in this group.[21] Further research is necessary to discover what kind of factors may serve as "cues" to obtain a mammogram among women who typically are infrequent users of the health-care system, particularly low income and ethnic minority populations.

The high cost of screening was the most frequently reported reason given by physicians for not recommending mammography for women in at-risk age groups. Although mammography is more expensive than some screening procedures, (average cost $125.00) the cost-effectiveness of early diagnosis for women over 50 years of age has been demonstrated in several studies.[21] Cost was not reported as a significant factor in this study group, although for most of these women the procedure was covered by insurance. Lack of coverage by Medicare may be a significant deterrent for women over 65 years of age. However, coverage by insurance policies may be increasing with awareness of the benefits of mammography.[21]

Table V
Source of Reinforcement

Source	*No.*	*%*
Health Professional	134	37.3
Relative	41	11.4
Friend	23	6.4
None	155	43.2

Since mammography is recommended annually for women over 50, it is important to insure the continuation of this health promoting behavior. The relationship of "rewards" or "reinforcers" to obtaining an initial mammogram and particularly to repeating the behavior requires further investigation. In this sample, after the procedure many women experienced a relief of tension and were verbally rewarded by health professionals, friends, or relatives. If a woman "feels good" about having a mammogram it is expected that she would be more likely to repeat the behavior, but determination of factors that are rewarding and their relationship to repeated behavior require further clarification.

Conclusion

In the past decade emphasis on preventive health behavior has increased, particularly in screening efforts to reduce deaths from cancer. Determination of factors that affect initial and continuing use of procedures such as mammography is essential. This descriptive study, using elements of models of preventive health behavior, examined three areas that potentially affect the use of mammography: 1) the role of information and perception of risk, 2) cues or events which initiate action, and 3) reinforcing events which reward the behavior. These results indicate that their physician's recommendation is essential for women's initial use of mammography. In addition, a physician's verbal reward or reinforcement of this action may be important to motivate women to maintain an appropriate schedule of mammograms. The ability of the primary physician to be effective in this key role is dependent on the availability and use of the most recent data on indications and guidelines for the use of mammography.

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Important Advances in Clinical Medicine

Occupational Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in occupational medicine. Each item, in the judgement of a panel of knowledgeable physicians, has recently become reasonably firmly established both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in occupational medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Occupational Medicine of the California Medical Association, and the summaries were prepared under its direction.

Electromagnetic Field Exposure and Risks of Cancer in Children

ALTHOUGH significant strides have been made in the past two decades in the treatment of and survival from a few cancers of childhood, cancer remains the second leading cause of death in children younger than 15 years. Thus, interest in the etiology of childhood cancers, and particularly in potentially preventable exposures that might be associated with these cancers, has also grown.

One area of increasing investigation relating to environmental exposures associated with the risk of childhood cancer is that of electromagnetic fields—that is, the magnetic fields generated by flowing electric currents. One of the earliest studies, published in 1979, found an association of high-current-flow electrical wiring configuration near the homes of children in Colorado with about a twofold increased risk of childhood cancer deaths (all types grouped) compared with matched controls. A report from Rhode Island, however, indicated no such excess risk for childhood leukemia. In another study from Colorado in 1988, an excess of in-home wire configuration codes indicating high magnetic field(>2 milligauss) was associated with all childhood cancer and a number of specific types of cancer compared with that in control children. In addition, a study from Texas found a greater frequency of paternal occupations (electronics workers) involving exposure to electromagnetic fields among children who had died of neuroblastoma than among randomly selected, live-birth controls. A 1986 Swedish publication also showed increased magnetic fields(>0.3 microtesla) around the dwelling of children with tumors compared with those of matched control children.

Scientific investigations into any increased risk of childhood cancer associated with either parental occupational exposures or home exposure to high-current electromagnetic fields have been plagued by a variety of methodologic limitations. These particularly include inadequate or biased methods of exposure assessment due to occupational groupings that are too broad; exposure information missing for large proportions of the study population; a lack of uniformity across studies in the timing of the exposure of interest—that is, at birth of the child, or at the time of the study; and a dependence on parental (especially maternal) recall of paternal occupations or occupational exposures. In addition, the inconsistency of findings may be due to a variation in the nature of the cases included. Some studies have selected newly diagnosed cases, but many studies have identified cases from death certificates, even though most of the cancers in question are not uniformly fatal. In addition, some studies have examined all cancers together, while others have examined specific types, such as leukemia, brain tumors, or neuroblastoma.

An assessment of our current understanding of the effects of environmental exposures on the risk of childhood cancer with these methodologic concerns leads to a conclusion that paternal occupational exposure to high-current electromagnetic fields may increase the risk and is of interest due to the ubiquity of this exposure and suggestions in studies of animals of the potential for a cancer-promoting effect. Further well-designed studies, however,

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with adequate sample size and exposure assessment and including only incident cases of specific types of cancer are needed.

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Isocyanates, Polyurethane Paints, and Asthma

THE isocyanates are important industrial chemicals used to make polyurethane plastics, which are common materials in our society. The cushioning for automobile seats and office and home furniture is usually polyurethane. Car bumpers are sometimes made of polyurethane. Polyurethane paints and coatings have found wide application in this country's economy because of their luster and resistance to weathering. All polyurethane paints contain diisocyanates or polyisocyanates, which are highly reactive low-molecular-weight compounds. The diisocyanate that previously was most commonly present in polyurethane products, toluene diisocyanate (TDI), has been the subject of extensive study in both laboratory and field studies.

The major adverse health effect associated with an occupational exposure to TDI is the induction of asthma. Although the mechanism of TDI-induced asthma is unclear, its clinical presentation often suggests that "sensitization" occurs. Cases of hypersensitivity pneumonitis associated with TDI exposure also have been reported. Toluene diisocyanate is a mucosal irritant in higher concentrations, and workers who have had exposure to it who do not appear to be "sensitized" have had accelerated annual rates of decline in ventilatory function. Nonspecific airway hyperresponsiveness has been induced in guinea pigs after single, short-term exposure to TDI at a concentration of 3 parts per million, suggesting that immunologic sensitization is not the only etiologic factor.

Contrary to the usual conception of occupational asthma, a persistence of asthmatic symptoms and nonspecific airway hyperresponsiveness after exposure ceases appears to be the norm rather than the exception with TDI-induced asthma. Many studies have confirmed this alarming potential of TDI exposure. Because the duration of asthmatic symptoms before diagnosis is associated with persisting symptoms after the cessation of exposure, there is a need for prompt diagnosis and the removal of affected workers.

Because of the health risks associated with TDI exposure, other diisocyanate compounds have been used in the manufacture of polyurethane paints and coating. In particular, hexamethylene diisocyanate is popular in automotive spray-painting applications. It is alleged by paint manufactures that hexamethylene diisocyanate is a less potent asthma-inducer than TDI, but case reports of asthma and hypersensitivity pneumonitis induced by this compound make this questionable.

In an effort to reduce exposure to "free" diisocyanate monomers in spray painting, manufacturers have developed paints consisting primarily of polyisocyanates ("prepolymers"). Although measured diisocyanate exposure in spray-painting areas may be reduced by the use of prepolymerized paints, it is not clear that such paints are completely without asthma-inducing potential. Our experience is that cases of occupational asthma due to the use of prepolymerized polyurethane spray paints do occur.

It is prudent to advise employers to provide, and workers to wear, appropriate respiratory protective gear in polyurethane spray-painting areas even if diisocyanate levels have been measured to be below the threshold limit value. It is not at all clear that the current threshold limit value will prevent the development of asthma.

Clinicians can also participate in the solution of this problem by identifying one of the isocyanates as the cause of adult-onset asthma. The immediate removal of the affected person from the work setting is likely to be an important factor in the prognosis.

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Health Hazards of Occupational Diesel Exhaust Exposure

DIESEL engines generate 50 to 100 times more particulates than do gasoline engines, and the organic extracts of diesel exhaust have been known since the 1950s to be carcinogenic in rodents. In the late 1970s the gasoline shortages and increasing number of light–duty diesel vehicles resulted in a heightened concern about the adverse health effects of diesel exhaust exposure. Since then numerous laboratory and epidemiologic studies have been completed addressing the issue.

Studies in the United States, Germany, and Japan have shown significant increases in lung tumors among rats with long-term exposure to high concentrations of diesel exhaust. Diesel exhaust carcinogenicity is both dose- and time-related. The mechanism of diesel carcinogenicity is thought to be the interaction of organic chemicals, particularly polycyclic aromatic hydrocarbons associated with diesel exhaust soot, with lung DNA. This is supported by recent studies showing higher levels of DNA adducts in the peripheral lung tissues of exposed rats, which is the location of diesel exhaust-induced lung tumors.

Diesel engines came into common industrial use in the 1940s and 1950s. Early epidemiologic studies were limited by inadequate latency times among exposed populations and poor estimates of diesel exposure. Many studies have also been limited by sample sizes too small to detect a small increase in lung cancer risk. Recent studies have addressed these limitations more adequately and have included populations with adequate sample sizes. An extensive series of studies among railroad workers in the United States found consistent evidence of a small but significant increase in lung cancer risk among current and former workers. For workers younger than 65 years with 20 years or more of exposure, the relative risk for lung cancer was approximately 1.3 to 1.4 compared with that of workers without such exposure. Studies among Canadian railroad workers and US truck drivers have had similar findings.

The laboratory and epidemiologic studies have resulted in the International Agency for Research on Cancer (IARC) recently concluding that there was sufficient evidence for carcinogenicity in animals of whole diesel engine exhaust and diesel engine exhaust particles. The IARC also concluded that there was limited evidence for carcinogenicity of diesel engine exhaust in humans. The risk from lifetime occupational exposure is small but biologically plausible and consistent with epidemiologic data. Populations at risk include persons whose occupations involve work in close proximity to operating diesel engines, such as railroad, bus, truck, and heavy equipment repair personnel and possibly operators. The data are limited on the possible interaction of diesel exhaust with other known lung carcinogens, including cigarette smoking.

There are few studies on the nonmalignant respiratory effects of occupational diesel exhaust exposure. Studies of miners have found an increase in some respiratory tract symptoms associated with diesel exhaust exposure, but no definite changes in pulmonary function have been found. Preliminary results of a mortality study have suggested that lifetime diesel exposure may be associated with increased chronic obstructive pulmonary disease mortality. More work is needed on the possible nonmalignant effects of workplace exposure to diesel exhaust.

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Health Hazards of Radon Exposure

RADON, a cause of lung cancer in miners of uranium and other underground minerals, has become recognized as a potentially important cause of lung cancer in the general population. This naturally occurring gaseous member of the uranium 238 decay series decays into a series of solid, short-lived isotopes referred to as radon daughters, progeny, or decay products. The release of α-particles by inhaled radon decay products is presumed to damage cells of the bronchial epithelium and thereby cause lung cancer.

As data on indoor air quality have accumulated, it has become apparent that radon and its decay products are present in indoor environments and at unacceptably high concentrations in some homes and other structures. Because the uranium-decay series is present in virtually all rocks and soils, radon contaminates the soil gas that passes into indoor and outdoor air. Thus in homes, the principal source of radon is the soil beneath the home, but building materials, water used in the home, and utility natural gas may also contribute. Measurements made in the United States indicate that the distribution of radon levels in houses is skewed, with the average at about 1.5 pCi per liter, but with many homes in the distribution's tail having much higher levels.

From animal and epidemiologic data, we have a sound understanding of some aspects of radon carcinogenesis. The lung cancer risk has been shown to increase with increasing exposure; the preponderance of the epidemiologic evidence indicates a synergism between cigarette smoking and radon exposure. The epidemiologic studies of underground miners provide the data needed to project the lung cancer risk of indoor exposure to radon. Computer models of the dosimetry of radon decay products in the lungs indicate a comparable potency of radon as a carcinogen with exposures in homes and in mines.

Although substantial uncertainty remains concerning the lung cancer risk associated with indoor radon, all projections indicate that the problem is substantial. Because carcinogenesis by radon is considered to follow a no-threshold exposure-response relation, any exposure, even the average for the population, conveys some risk. Remarkably high risks of lung cancer are projected for high exposures. For the US population, estimates of the annual number of lung cancer cases attributable to radon range from about 5,000 to 20,000 cases.

Health care providers should be prepared to advise patients concerning the risks of indoor radon and not dismiss the problem. Following the 1988 advisory of the Environmental Protection Agency (EPA). the measurement of radon in homes should be advocated. We lack other methods for identifying homes with unacceptable concentrations. Longer term measurements, rather than shorter term measurements with a charcoal canister, are preferred under most circumstances. The results of measurements should be interpreted cautiously, but mitigation should be advised for homes with high levels. The EPA's guidelines offer one framework for interpreting measurements, but the highest acceptable level-4 pCi per liter-is not a boundary between safe and unsafe levels. Smokers should be cautioned about the synergism between smoking and radon exposure and advised to stop smoking.

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Male Reproductive Toxicity

WORK-RELATED birth disorders are commonly regarded as related to the occupational experiences of pregnant women. Evidence suggests, however, that toxic exposures in men can also influence reproduction. There are many theoretic mechanisms by which this might occur: a pregnant woman might have direct exposure to a toxin inadvertently transported home from the workplace; a systemic, endocrine, or testicular toxic reaction could impair the male libido or fertility; and systemically absorbed chemicals that cross the blood-testis barrier or are secreted into seminal fluids might either damage sperm or directly affect a fetus or oocyte through sexual transmission.

A number of workplace chemicals have been reported to cause sperm abnormalities. Lead exposure, for example, has been shown in a study of 150 male storage battery workers to be dose-related to the prevalence of oligospermia, sperm hypomotility,and abnormal sperm characteristics. Exposures to boron, cadmium, manganese, and mercury have each been linked to sperm abnormalities, but these data come from small studies or case reports and are inconclusive. Abnormal spermatogenesis has also been described in epidemiologic studies of men with exposure to certain organic compounds, including carbon disulfide, chloroprene, dinitrotoluene and toluene diamine, and the pesticides carbaryl, chlordecone, and dibromochloropropane (DBCP). In many instances the sperm abnormalities have been of indeterminate clinical significance, but human exposures to lead and to DBCP have produced infertility, and the more severe cases of DBCP have produced DBCP spermatotoxicity have been irreversible. There is generally minimal information from studies in humans or animals with which to judge the potential spermatotoxicity of the thousands of other commonly used industrial chemicals.

Many authorities question whether paternal chemical exposures can influence a partner's pregnancy outcome or cause abnormalities that are transmissible to offspring. but there is evidence that such adverse effects occur. Paternal exposures to lead, chloroprene, and DBCP have each been reported to increase rates of spontaneous abortion. Other epidemiologic studies have also suggested, for example, that partners of male anesthetists and of copper smelter workers are at a risk for spontaneous fetal loss and that paternal "hydrocarbon" exposure may increase the occurrence of low birth weight, central nervous system malformations, and childhood cancers. Although few human studies have been confirmed with subsequent studies, they are supported in principle by the findings of animal research in which exposures of male animals to various alkylating agents have subsequently produced genetic mutations, chromosomal translocations, malformations, and tumors detectable in first- and, in some studies, second-generation offspring.

There is a paucity of data regarding male reproductive toxicity, but the implications of the available data are broad. Workplace exposures should be considered in evaluating male infertility. Men attempting to start a family should be counseled to minimize chemical exposures. Finally, efforts to reduce workplace exposures to known or suspected reproductive toxins should be extended to both men and women.

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Ethylene Oxide Carcinogenicity

ETHYLENE oxide (CHO) is an important industrial chemical used in sterilization and many manufacturing processes. At ambient temperatures it is a gas. In vivo it is rapidly distributed throughout the body. Short- and long-term exposures may lead to respiratory irritation, central nervous system depression, and seizures. At high concentrations ethylene oxide can induce lethal mutations and is embryotoxic in animals. Ethylene oxide is able to alkylate DNA, causing gene mutations that lead to sister chromatid exchange abnormalities and chromosomal damage.

Ethylene oxide has been found carcinogenic in animals following subcutaneous, oral, and inhalation administration. Following oral administration, ethylene oxide produces an increase in local tumors, most notably squamous cell carcinoma of the forestomach in rats. Following inhalation ethylene oxide produces a substantial increase in the incidence of mononuclear cell leukemia in male and female rats and in that of peritoneal mesotheliomas in male rats. An increase in the incidence of brain tumors (rarely found in control animals) is also noted in male rats with exposure to ethylene oxide by inhalation.

Epidemiologic evidence shows an association between the exposure of humans to ethylene oxide and some forms of cancer. An excess of leukemia mortality has been reported in several epidemiologic studies, but these studies do not provide conclusive evidence for this association owing to the small number of workers studied and the possibility of exposure of the workers to other carcinogens. These studies, however, do provide some evidence for ethylene oxide's carcinogenicity in humans.

In 1985 the International Agency for Research in Cancer concluded that there is sufficient evidence for the carcinogenicity of ethylene oxide in animals and that the evidence of carcinogenicity in humans is limited. Overall, the review of this information suggests that the data on both animals and humans is sufficient to classify ethylene oxide as probably carcinogenic in humans.

In light of the importance of sterilizing medical equipment, especially with the danger of human immunodeficiency virus and hepatitis B infection, ethlylene oxide will continue to be widely used. Human exposure to ethylene oxide should be kept as low as feasible given present-day technology. Health personnel working in close proximity to ethylene oxide should be given proper training as to ethylene oxide's dangers and be informed as to the known and uncertain risks of ethylene oxide exposure. The function of sterilizing equipment should be regularly assessed, proper ventilation established, and alarm systems installed.

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Occupational Back Pain of Nurses

HEALTH care workers are potentially subject to a large number of occupational health hazards, ranging from carcinogens and mutagens such as ethylene oxide and chemotherapeutic agents to the effects of rotating shift assignments. Musculoskeletal disorders are also prominent among the problems faced by health care providers. Occupational back pain among nursing staff is common and leads to a considerable loss of valuable nurses. Epidemiologic studies in several countries—England, United States, Denmark, Israel—provide rather uniform estimates of the high frequency of such illnesses. An analysis of workers' compensation claims suggests that acute care hospital nurses are at particularly high risk. For example, registered nurses are 5.1 times as likely to have back-related compensation claims as are cashiers, and nurses' aides are 22 times as likely.

In the past, much effort has been expended in training student nurses in the "proper-lift" technique to be used in patient transfers. There are several reasons why this has not succeeded in controlling the problem: First, the techniques taught may actually increase low-back stress. Second, other nursing activities besides lifting patients—such as moving equipment and standing in awkward position for prolonged periods—may also be important in producing these problems. Third, such training may account for the attitude of many nurses that they are personally responsible for preventing their own health problems, thereby directing attention away from environmental factors. Fourth, many lifting assistance devices, such as the Hoyer lift, are awkward to use and so are underused. Fifth, hospital staffing patterns may not permit the use of two-person lifts. Sixth, understaffing and changes in work schedules, particularly the use of 12-hour shifts may be exacerbating musculoskeletal work stresses. Finally, counting on workers to modify their work practices to decrease occupational injury and illness rates is generally less effective than appropriate environmental modifications. Successful intervention programs require a major commitment to providing help for individual nurses rather than providing "training" in groups.

Although back injury rates of nurses approach those of truckers and warehouse workers, nurses have a fundamentally different problem because they may risk injury to themselves in order to preserve and improve the health of their patients. In addition to continuing traditional proper-lift training and providing symptomatic treatment, it is important to encourage the proper reporting of nursing injuries, to encourage nurses to analyze their activities carefully, to apply well-known industrial ergonomic principles to hospital and hospital equipment design, and to consider carefully the effects of scheduling and staffing changes. It is also essential to develop effective rehabilitation and limited-duty opportunities for nurses with back injuries. This mandate is particularly important in view of the increasingly severe nursing shortage; medicine can no longer afford the high attrition rates, absenteeism (often underreported), and impaired work performance caused by discomfort, medication use, or both. Back pain is solely responsible for 1.3% of those quitting nursing and was a "major" contribution to an additional 12% of those leaving.

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Occupational Liver Disease

ALTHOUGH a number of industrial chemicals are known hepatotoxins, liver disease from occupational exposure is rarely suspected or diagnosed. Well-recognized hepatotoxins such as carbon tetrachloride, trinitrotoluene, and yellow phosphorus are no longer widely used, but numerous other organic solvents and chemicals that are known or suspected hepatotoxins are used extensively throughout industry. Several recent reports provide evidence that occupational liver injury may occur more frequently than is generally recognized. These reports help to both characterize occupational hepatotoxicity and suggest ways to distinguish it from other forms of liver disease.

An outbreak of liver disease among workers with routine exposure to a widely used solvent, dimethylformamide, was recently reported. After the index case presented with hepatitis, 35 of 46 co-workers (76%) were found to have elevated levels of liver aminotransferases, several more than tenfold. Although variably symptomatic, most of these workers had not sought medical attention. The alanine aminotransferase (ALT) level was higher than the aspartate aninotransferase (AST) level in all but one worker, a finding atypical for alcoholic liver disease. Evaluation of the workplace, a plant that produces polyurethane-coated fabrics, showed that large quantities of dimethylformamide, a known hepatotoxin, were being used in poorly ventilated areas and without appropriate skin protection. Most of the workers' aminotranferase values improved with removal from exposure, and no new cases have been detected since improvements were made in the workplace. Liver biopsy specimens from several of the workers showed histologic feature consistent with hepatotoxic injury. Findings included hepatocellular necrosis and microvesicular steatosis acutely and pronounced steatosis in those with more long-term exposure.

Other recent reports have documented hepatotoxic effects among workers with exposure to several different widely used solvents. Steatosis and elevated liver amniotransferase levels have been found among painters with exposure to various organic solvents. Similar findings were recently described among four workers with exposure to the solvent 1,1,1-trichloroethane. Fulminant hepatic necrosis after occupational exposure to 2-nitropropane has also been reported recently.

These studies suggest that occupationally induced liver injury does occur in modern industry, most commonly in workers with exposure to solvents, and that a high index of suspicion is necessary to make the diagnosis. The findings of elevated levels of aminotransferases, especially with the ALT higher than the AST, should alert clinicians to consider such a possibility. Necrosis or steatosis on a liver biopsy specimen, while nonspecific, is also suggestive of possible occupational liver injury. When other likely causes of liver disease—that is, viral and alcohol-induced—have been reasonably excluded, removal from potential hepatotoxic exposures should be seriously considered. The resolution of liver function abnormalities after removal from such exposure provides further support for an occupational origin. The natural history of mildly elevated amniotransferase values in the occupational setting is unclear, however, making it difficult to establish firm guidelines for removal. A strong suspicion of occupationally induced liver disease should prompt an industrial hygiene evaluation of the workplace and appropriate modifications of work practices, such as improved ventilation, appropriate protective clothing, and product substitution, to reduce potentially toxic exposures. Whether prolonged exposure to currently used hepatotoxic chemicals can cause chronic liver injury and cirrhosis is an important question that needs further study.

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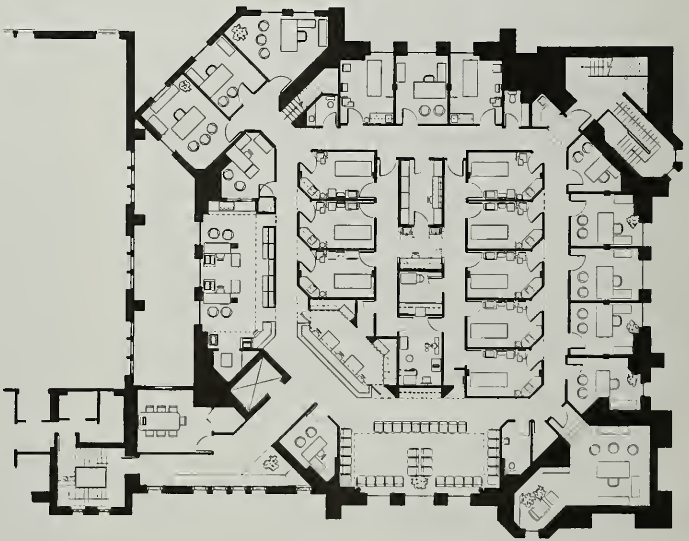

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Noise and Hearing Loss

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Introduction

HEARING loss afflicts approximately 28 million people in the United States. Approximately 10 million of these impairments are at least partially attributable to damage from exposure to loud sounds. Sounds that are sufficiently loud to damage sensitive inner-ear structures can produce hearing loss that is not reversible by any presently available medical or surgical treatment. Hearing impairment associated with noise exposure can occur at any age, including early infancy, and is often characterized by difficulty in understanding speech and the potentially troublesome symptom, tinnitus (ie, ringing in the ears). Very loud sounds of short duration, such as an explosion or gunfire, can produce immediate, severe, and permanent loss of hearing. Longer exposure to less intense but still hazardous sounds, commonly encountered in the workplace or in certain leisure time activities, exacts a gradual toll on hearing sensitivity, initially without the victim's awareness. More than 20 million Americans are exposed on a regular basis to hazardous noise levels that could result in hearing loss. Occupational noise exposure, the most common cause of noise-induced hearing loss (NIHL), threatens the hearing of firefighters, police officers, military personnel, construction and factory workers, musicians, farmers, and truck drivers, to name a few. Live or recorded high-volume music, recreational vehicles, airplanes, lawcare equipment, woodworking tools, some household appliances, and chain saws are examples of nonoccupational sources of potentially hazardous noise. One important feature of NIHL is that it is preventable in all but certain cases of accidental exposure. Legislation and regulations have been enacted that spell out guidelines for protecting workers from hazardous noise levels in the workplace and consumers from hazardous noise during leisure time pursuits. Inconsistent compliance and spotty enforcement of existing Governmental regulations have been the underlying cause for their relative ineffectiveness in achieving prevention of NIHL. A particularly unfortunate occurrence was the elimination of the Office of Noise Abatement and Control within the Environmental Protection Agency in 1982.

On 22-24 January 1990, the National Institute on Deafness and Other Communication Disorders, together with the Office of Medical Applications of Research of the National Institutes of Health convened a Consensus Development Conference on Noise and Hearing Loss. Cosponsors of the conference were the National Institute of Child Health and Human Development, the National Institute on Aging, and the National Institute for Occupational Safety and Health of the Centers for Disease Control. The effects of environmental sounds on human listeners may include:

- Interference with speech communication and other auditory signals.
- Annoyance and aversion.
- Noise-induced hearing loss.
- Changes in various body systems.
- Interference with sleep.

This conference was entirely centered on NIHL. The panel focused on five questions related to noise and hearing loss?

- What is noise-related hearing loss?
- What sounds can damage hearing?
- What factors, including age, determine an individ-

NIH Consensus Development Conferences are convened to evaluate available scientific information and to resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

NIH Consensus Statements are prepared by a nonadvocacy, nonfederal panel of experts based on (1) presentations by investigators working in areas relevant to the consensus questions during a 1½-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and the morning of the third day. This statement is an independent report of the panel and is not a policy statement of the NIH or the federal government.

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ual's susceptibility to noise-related hearing loss?

- What can be done to prevent noise-related hearing loss?
- What are the directions for future research?

Following a day and a half of presentations by experts in the relevant fields and discussion from the audience, a consensus panel comprising specialists and generalists from the medical and other related scientific disciplines, together with public representatives, considered the evidence and formulated a consensus statement in response to the five previously stated questions.

1. What is Noise-Induced Hearing Loss?

Sounds of sufficient intensity and duration will damage the ear and result in temporary or permanent hearing loss. The hearing loss may range from mild to profound and may also result in tinnitus. The effect of repeated sound overstimulation is cumulative over a lifetime and is not currently treatable. Hearing impairment has a major impact on one's communication ability and even mild impairment may adversely affect the quality of life. Unfortunately, although NIHL is preventable, our increasingly noisy environment places more and more people at risk.

Studies of NIHL

Most studies of the association between sound exposure and hearing loss in humans are retrospective measurements of the hearing sensitivities of numerous individuals correlated with their noise exposures. The variability within these studies is usually large; thus, it is difficult to predict the precise magnitude of hearing loss that will result from a specific sound exposure. Prospective studies of selected workers' hearing levels over a long time while their sound exposures are carefully monitored are costly and time-consuming and, due to attrition, require a large number of subjects. When significant hearing loss is found, for ethical reasons, exposures must be reduced, interfering with the relationships under study. Although studies of NIHL in humans are difficult, they provide valuable information not available from animals studies and should be continued.

In prospective animals studies, sound exposures can be carefully controlled, and the anatomic and physiologic correlates of NIHL can be precisely defined. Although there may be interspecies differences with respect to the absolute sound exposure that will injure the ear, the basic mechanisms that lead to damage appear to be similar in all mammalian ears.

Anatomic and Physiologic Correlates of NIHL

Two types of injury are recognized: acoustic trauma and NIHL. Short-duration sound of sufficient intensity (eg, a gunshot or explosion) may result in immediate, severe, and permanent hearing loss, which is termed acoustic trauma. Virtually all of the structures of the ear can be damaged, in particular the organ of Corti, the delicate sensory structure of the auditory portion of the inner ear (cochlea), which may be torn apart.

Moderate exposure may initially cause temporary hearing loss, termed temporary threshold shift (TTS). Structural changes associated with TTS have not been fully established but may include subtle intracellular changes in the sensory cells (hair cells) and swelling of the auditory nerve endings. Other potentially reversible effects include vascular changes, metabolic exhaustion, and chemical changes within the hair cells. There is also evidence of a regional decrease in the stiffness of the stereocilia (the hair bundles at the top of the hair cells), which may recover. This decrease in stereocilia stiffness may lead to a decrease in the coupling of sound energy to the hair cells, which thereby alters hearing sensitivity.

Repeated exposure to sounds that cause TTS may gradually cause permanent NIHL in experimental animals. In this type of injury, cochlear blood flow may be impaired, and a few scattered hair cells are damaged with each exposure. With continued exposure, the number of damaged hair cells increases. Although most structures in the inner ear can be harmed by excessive sound exposure, the sensory cells are the most vulnerable. Damage to the stereocilia is often the first change, specifically, alteration of the rootlet structures that normally anchor the stereocilia into the top of the hair cell. Once destroyed, the sensory cells are not replaced. During the recovery period between some sound exposures, damaged regions of the organ of Corti heal by scar formation. This process is very important because it reestablishes the barrier between the two fluids of the inner ear (perilymph and endolymph). If this barrier is not reestablished, degeneration of hair cells may continue. Further, once a sufficient number of hair cells are lost, the nerve fibers to that region also degenerate. With degeneration of the cochlear nerve fibers, there is corresponding degeneration within the central nervous system. The extent to which these neural changes contribute to NIHL is not clear.

With moderate periods of exposure to potentially hazardous high-frequency sound, the damage is usually confined to a restricted area in the high-frequency region of the cochlea. With a comparable exposure to low-frequency noise, hair cell damage is not confined to the low-frequency region but may also affect the high-frequency regions. The predominance of damage in different cochlear regions with different frequency exposures reflects factors such as the resonance of the ear canal, the middle-ear transfer characteristics, and the mechanical characteristics of the organ of Corti and basilar membrane.

Assessment of NIHL

Hearing loss is measured by determining auditory thresholds (sensitivity) at various frequencies (pure-tone audiometry). Complete assessment should also include measures of speech understanding and middle-ear status (immittance audiometry). Pure-tone audiometry is also used in industrial hearing conservation programs to determine whether adequate protection against hazardous sound levels is provided.

The first audiometric sign of NIHL resulting from broadband noise is usually a loss of sensitivity in the higher frequencies from 3,000 through 6,000 Hertz (Hz) (ie, cycles per second), resulting in a characteristic audiometric "notch." With additional hearing loss from noise or aging, the threshold at 8,000 Hz may worsen and eliminate this characteristic audiometric pattern. Thus, the presence or absence of NIHL cannot be established on the basis of audiometric shape, per se. The hearing loss is usually bilateral, but some degree of asymmetry is not unusual, especially with lateralized noise sources such as rifles. After moderate sound exposure, TTS may occur, and, during a period of relative quiet, thresholds will return to normal levels. If the exposure continues on a regular basis, permanent threshold shifts (PTS) will result, increasing in magnitude and extending to lower and higher frequencies. If the exposures continue, NIHL increases, more rapidly in the early years. After many years of exposure, NIHL levels off in the high frequencies, but continues to worsen in the low frequencies. Although TTS and PTS are correlated, the relation is not strong enough to use TTS to predict the magnitude of permanent hearing loss.

An important consequence of the sensitivity loss associated with NIHL is difficulty in understanding speech. Whereas a large proportion of the *energy* in speech is contained within the low-frequency range, much of the *information* required to differentiate one speech sound from another is contained within the higher frequencies. With significant hearing loss in the high frequencies, important speech information is often inaudible or unusable. Other interfering sounds such as background noise, competing voices, or room reverberation may reduce even further the hearing-impaired listener's receptive communication ability. The presence of tinnitus may be an additional debilitating condition.

NIHL may interfere with daily life, especially those social activities that occur in noisy settings. Increased effort is required for understanding speech in these situations, which leads to fatigue, anxiety, and stress. Decreased participation in these activities often results, affecting not only hearing-impaired individuals but also friends and family members. Hearing loss is associated with depression in the elderly and may be related to dementia and cognitive dysfunction. Systematic study of the effects of hearing loss on the quality of life have only lately focused specifically on individuals with NIHL; therefore, continued studies of this kind are desirable.

The impairment in hearing ability resulting from NIHL may vary from mild to severe. An individual's ability to communicate and function in daily life varies with the degree of loss and the individual's communication needs although these relationships are complex. The magnitude of the effect on communication ability may be estimated by a variety of scales, which are often used in disability determinations. These scales, which vary substantially in frequencies used, the upper and lower limits of impairment, age correction, and adjustment for asymmetric hearing loss, attempt to predict the degree of communication impairment (understanding of speech) on the basis of pure-tone thresholds. There is no consensus about the validity or utility of the scales, which scale should be used, whether measures of speech understanding should be included, or whether self-assessment rating should be incorporated into either impairment rating scales or disability determinations.

2. What Sounds Can Damage Hearing?

Some sounds are so weak physically that they are not heard. Some sounds are audible but do not have any temporary or permanent after-effects. Some sounds are strong enough to produce a temporary hearing loss from which there may appear to be complete recovery. Damaging sounds are those that are sufficiently strong, sufficiently long-lasting, and involve appropriate frequencies so that permanent hearing loss will ensue.

Most of the sounds in the environment that produce such permanent effects occur over a very long time (for example, about 8 hours per workday over a period of 10 or more years). On the other hand, there are some particularly abrupt or explosive sounds that can cause damage even with a single exposure.

The line between these categories of sounds cannot be stated simply because not all persons respond to sounds in the same manner. Thus, if a sound of given frequency bandwidth, level, and duration is considered hazardous, one must specify for what proportion of the population it will be hazardous and, within that proportion, by what criterion of damage (whether anatomical, audiometric, or speech understanding) it is hazardous.

The most widely used measure of a sound's strength or amplitude is called "sound level," measured by a sound-level meter in units called "decibels" (dB). For example, the sound level of speech at typical conversational distances is between 65 and 70 dB. There are weaker sounds, still audible, and of course much stronger sounds. Those above 85 dB are potentially hazardous.

Sounds must also be specified in terms of frequency or bandwidth, roughly like the span of keys on a piano. The range of audible frequencies extends from about 20 Hz, below the lowest notes on a piano, to at least 16,000 or 20,000 Hz, well above the highest notes on a piccolo. Most environmental noises include a wide band of frequencies and, by convention, are measured through the "A" filter in the sound-level meter and thus are designated in dB(A) units. It is not clear what effect, if any, sound outside the frequency range covered in dB(A) measurements may have on hearing. At this time, it is not known whether ultrasonic vibration will damage hearing.

To define what sounds can damage hearing, sound level, whether across all frequency bands or taken band by band, is not enough. The duration of exposure—typical for a day and accumulated over many years—is critical. Sound levels associated with particular sources such as snowmobiles, rock music, and chain saws, are often cited, but predicting the likelihood of NIHL from such sources also requires knowledge of typical duration and the number of exposures.

There appears to be reasonable agreement that sound levels below 75 dB(A) will not engender a permanent hearing loss, even at 4000 Hz. At higher levels, the amount of hearing loss is directly related to sound level for comparable durations.

According to some existing rules and regulations, a noise level of 85 dB(A) for an eight-hour daily exposure is potentially damaging. If total sound energy were the important predictor, an equivalent exposure could be as high as 88 dB(A) if restricted to 4 hours. (A 3-dB increase is equivalent to doubling the sound intensity.) This relation, enshrined in some standards and regulations, is a theory based on a dose or exposure defined by total energy.

In spite of the physical simplicity of a total-energy concept, other principles have been invoked to define equivalent exposures of different sound levels and durations. Early research suggested that NIHL after 10 years could be predicted from temporary threshold shifts (TTS) measured 2 minutes after a comparable single-day exposure. Those results, however, were taken to indicate that halving a duration could be offset by a 5-dB change in sound level rather than a 3-dB change. This 5-dB rule is implemented in the Walsh-Healey Act of 1969 and subsequent OSHA regulations for the purpose of requiring preventive efforts for noise-exposed workers. The 3-dB trading rule is agreed to in International Standards Organization (ISO) Standard 1999.2 (1989) for the purpose of predicting the amount of noise-induced loss resulting from different exposures. There is no consensus concerning a single rule to be used for all purposes in the United States.

Generally, for sound levels below about 140 dB, different temporal forms of sound, whether impulse (gunshot), impact (drop forge), or steady state (turbine), when specified with respect to their level and duration, produce the same hearing loss. This does not appear to follow at levels above 140 dB, where impulse noise creates more damage than would be predicted. This may imply that impulse noise above a certain critical level results in acoustic trauma from which the ear cannot recover.

Although sound exposures that are potentially hazardous to hearing are usually defined in terms of sound level, frequency bandwidths, and duration, there are several simple approximations which indicate that a sound exposure may be suspected as hazardous. These include the following: If the sound is appreciably louder than conversational level, it is potentially harmful, provided that the sound is present for a sufficient period of time. Hazardous noise may also be suspected if the listener experiences: a) difficulty in communication while in the sound, b) ringing in the ear (tinnitus) after exposure to the sound, and/or c) the experience that sounds seem muffled after leaving the sound-exposure area.

In the consideration of sounds that can damage hearing, one point is clear: it is the acoustic energy of the sound reaching the ear, not its source, which is important. That is, it does not matter if the hazardous sound is generated by a machine in the workplace, by an amplifier/loudspeaker at a rock concern, or by a snowmobile ridden by the listener. Significant amounts of acoustic energy reaching the ear will create damage—at work, at school, at home, or during leisure activities. Although there has been a tendency to concentrate on the more significant occupational and transportation noise, the same rule apply to all potential noise hazards.

3. What Factors, Including Age, Determine an Individual's Susceptibility to Noise-Related Hearing Loss?

One thoroughly established characteristic of NIHL is that, on the average, more intense and longer-duration noise exposures cause more severe hearing loss. A second is that there is a remarkably broad range of individual differences in sensitivity to any given noise exposure. Several factors have been proposed to explain differences in NIHL among individuals; others may be associated with differences over time within the same individual. It is important to distinguish those factors whose roles in determining susceptibility are supported by a consistent body of theory and empirical evidence from other factors whose roles have been proposed but for which theory, data, or both are less conclusive.

Differences Among Individuals

Both temporary threshold shift (TTS) and permanent threshold shift (PTS) in response to a given intense noise may differ as much as 30 to 50 dB among individuals. Both animal research and retrospective studies of humans exposed to industrial noise have demonstrated this remarkable variation in susceptibility. The biological bases for these differences are unknown. A number of extrinsic factors (eg, characteristics of the ear canal and middle ear, drugs, and prior exposure to noise) may influence an individual's susceptibility to NIHL. However, animal studies that have controlled these variables suggest that individual differences in inner ear anatomy and physiology also may be significant. Additional research is necessary to determine whether vascular, neural feedback (efferent system), or other mechanisms can account for and predict such individual variation.

One factor that may be associated with decreased susceptibility to NIHL is conductive hearing loss; the cochlear structures may be protected by any form of acoustic attenuation. For similar reasons, middle ear muscles, which normally serve a protective function by contracting in response to intense sound, when inoperative, can result in increased susceptibility. Among the other factors that are *theoretically* associated with differences in susceptibility are (a) unusually efficient acoustic transfer through the external and middle ear, as a determinant of the amount of energy coupled to the inner ear structures, and (b) preexisting hearing loss, which could imply that less additional loss would occur if the sensitive structures have already been damaged. Support for these hypotheses has been modest, in the case of the transfer function, because little empirical work has been done to test that hypothesis, and, in the case of reduced sensitivity, because several studies disagree. In general, when there is a difference in average loss to a given noise exposure, those ears with previous PTS or TTS have shown somewhat less additional loss than those not previously exposed.

Findings have sometimes implicated degree of pigmentation, both of the receptor structures (melanization) and of the eye and skin, as related to susceptibility. However, these results too are equivocal.

Gender

There is little difference in hearing thresholds between young male and female children. Between ages 10 and 20, males begin to show reduced high-frequency auditory sensitivity relative to females. Women continue to demonstrate better hearing than men into advanced age. These gender differences are probably due to greater exposure of males to noise rather than to their inherent susceptibility to its effects.

Differences Within Individuals

Ototoxic Drugs

Among the causes of differences of susceptibility to noise exposure *within* individuals are ototoxic drugs and other chemicals. In animal research, certain antibiotics (aminoglycocides) appear to exacerbate the damaging effects of noise exposure. Clinical evidence of corresponding effects in human patients has not been established, but precautions should be taken with regard to noise exposures of individual patients treated with these medications. Although high doses of aspirin are widely known to cause TTS and tinnitus, aspirin has *not* been shown to increase susceptibility of NIHL.

Age

In certain animal models there is evidence of heightened susceptibility to noise exposure shortly after birth—a "critical period" (possibly following the time when fluids fill the middle ear but before complete development of the cochlear structures). However, it is *not* clear that data from such animal models can be generalized to full-term normal human infants. Premature infants in noisy environments (eg, neonatal intensive care units), however, may be at risk.

At the other extreme, increasing age has been hypothesized to be associated with decreasing susceptibility. This contention is based on the existence of presbycusis, hearing loss that increases with age and that is *not* known to be attributable to excessive noise exposure or other known etiology. The typical levels of presbycusis at various ages have recently been incorporated as Annex A in International Standards Organization Standard 1999.2 (1989). That standard may be used to estimate the portion of overall hearing loss that is attributable to exposure to excessive noise.

In summary, scientific knowledge is currently inadequate to predict that any individual will be safe in noise that exceeds established damage-risk criteria, nor that specific individuals will show greater-than-average loss following a given exposure. Among the many proposed explanations, the hypothesis that the resonant and transmission properties of the external and middle ear affect individual susceptibility deserves further attention. Empirical support for this hypothesis should not be difficult to obtain, but very few data have been collected on this question, both for TTS (experimentally) and PTS (retrospectively). Differences in susceptibility of the cochlear structures to NIHL may exist, but no practical approach to predicting them is yet available. Identification of susceptible humans will almost certainly be delayed until a successful animal model is available.

4. What Can Be Done to Prevent Noise-Related Hearing Loss?

Noise-induced hearing loss occurs every day—in both occupational and nonoccupational settings. The crucial questions for prevention are as follows: 1) What can individuals do to protect themselves from NIHL? 2) What role should others, such as educators, employers, or the Government, play in preventing NIHL? 3) What general strategies should be employed to prevent NIHL? Answers to these questions have long been known, but solutions have not been effectively implemented in many cases. As a result, many people have needlessly suffered hearing loss.

Individual Protection Strategies

Hearing conservation must begin by providing each individual with basic information. NIHL is insidious, permanent, and irreparable, causing communication interference that can substantially affect the quality of life. Ringing in the ears and muffling of sounds after sound exposure are indicators of potential hazard. Dangerous sound exposures can cause significant damage without pain and hearing aids do not restore normal hearing. Individuals should become aware of loud noise situations and avoid them if possible or properly use hearing protection. It is important to recognize that both the level of the noise and its duration (ie, exposure) contribute to the overall risk. Certain noises, such as explosions, may cause immediate permanent damage.

Many sources, such as guns, power tools, chain saws, small airplanes, farm vehicles, firecrackers, some types of toys, and some medical and dental instruments may produce dangerous exposures. Music concerts, car and motorcycle races, and other spectator events often produce sound levels that warrant hearing protection. Similarly, some stereo headphones and loudspeakers are capable of producing hazardous exposures. Parents should exercise special care in supervising the use of personal headset listening devices, and adults and children alike should learn to operate them at safe volume settings.

Nonoccupational Strategies

Hearing loss from nonoccupational noise is common, but public awareness of the hazard is low. Educational programs should be targeted toward children, parents, hobby groups, public role models, and professionals in influential positions such as teachers, physicians, audiologists and other health care professionals, engineers, architects, and legislators. In particular, primary health physicians and educators who deal with young people should be targeted through their professional organizations. Consumers need guidance and product noise labeling to assist them in purchasing quieter devices and in implementing exposure reduction strategies. The public should be made aware of the availability of affordable, effective hearing protectors (ear plugs, ear muffs, and canal caps). Hearing protection manufacturers should supply comprehensive instructions concerning proper protecter use and also be encouraged to increase device availability to the public sector. Newborn nurseries, including neonatal intensive care units, should be made quieter. Medical and dental personnel should be trained to educate their patients about NIHL.

Individuals with significant noise exposure need counseling. Basic audiometric evaluations should be widely available. The goal is to detect early noise-induced damage and interrupt its progression *before* hearing thresholds exceed the normal range.

Occupational Strategies

Hearing conservation programs for occupational settings must include the following interactive components: sound surveys to assess the degree of hazardous noise exposure, engineering and administrative noise controls to reduce exposures, education to inform at-risk individuals why and how to prevent hearing loss, hearing protection devices (earplugs, earmuffs, and canal caps) to reduce the sound reaching the ear, and audiometric evaluations to detect hearing changes. Governmental regulations that currently apply to most noisy industries should be revised to encompass *all* industries and all employees, strengthened in certain requirements, and strictly enforced with more inspections and more severe penalties for violations.

Many existing hearing conservation programs remain ineffective due to poor organization and inadequately trained program staff. Senior management must use available noise controls, purchase quieter equipment, and incorporate noise reduction in planning new facilities. Noise exposures must be measured accurately and the degree of hazard communicated to employees. Hearing protection devices must be available that are comfortable, practical for the demands of work tasks, and provide adequate attenuation. Labeled ratings of hearing protector attenuation must be more realistic so that the degree of protection achieved in the workplace can be properly estimated. Each employee must be individually fitted with protectors and trained in their correct use and care. Employees need feedback about their audiometric monitoring results annually.

Employers need to monitor program effectiveness by using appropriate techniques for analysis of group audiometric data. By detecting problem areas, managers can prioritize resource allocations and modify company policies to achieve effectiveness. Potential benefits include reduced costs for worker's compensation, enhanced worker morale, reduced absenteeism, fewer accidents, and greater productivity.

Enactment of uniform regulations for awarding worker's compensation for occupational hearing loss would stimulate employers' interest in achieving effective hearing conservation programs. Equitable criteria for compensability should be developed based on scientific investigations of the difficulties in communication and other aspects of auditory function encountered in everyday life by persons with differing degreees of NIHL.

General Strategies

Both nonoccupational and occupational NIHL could be reduced by implementing broader preventive efforts. Labeling of consumer product noise emission levels should be enforced according to existing regulations. Incentives for manufacturers to design quieter industrial equipment and consumer goods are needed along with regulations governing the maximum emission levels of certain consumer products, such as power tools. Reestablishment of a Federal agency coordinating committee with central responsibility for practical solutions to noise issues is essential. Model community ordinances could promote local planning to control environmental noise and, where feasible, noise levels at certain spectator events. High-visibility media campaigns are needed to develop public awareness of the effects of noise on hearing and the means for self-protection. Prevention of NIHL should be part of the health curricula in elementary through high schools. Self-education materials for adults should be readily available.

5. What Are the Directions for Future Research?

The panel recommends that research be undertaken in two broad categories: (1) Studies which use existing knowledge to prevent NIHL in the immediate future, and; (2) Research on basic mechanisms to prevent NIHL in the long-term future.

- Development of rationale and collection of empirical data to evaluate systems for combining sound level and duration to predict NIHL.
- Longitudinal studies to further delineate responses of the ear to noise over time in different groups of people with varying levels of exposure.
- Continued investigation of engineering noise measurement and control techniques, such as acoustic intensity measurement, active noise-cancellation systems, and cost-benefit analyses of noise reduction.
- Development and investigation of hearing protector designs that provide improved wearer comfort, usability, and more natural audition.
- Development of repeatable laboratory procedures that incorporate behavioral tests to yield realistic estimates of hearing protector attenuation performance that are accepted for device labeling purposes.
- Empirical evaluation of the efficacy of hearing conservation programs and the field performance of hearing protection devices in industry.

- Development and validation of evaluation techniques for detection of the following: a) subtle changes in hearing resulting from noise exposure and b) early indicators of NIHL.
- Determination of the pathophysiological correlates of TTS and PTS.
- Investigation of the anatomic and physiologic bases of presbycusis and interactive effects with NIHL.
- Investigation of genetic bases for susceptibility to NIHL, using contemporary techniques, including molecular biology.
- Further studies of drugs (eg, vasodilating agents) and other pre-exposure conditions (eg, activation of efferent systems or exposure to "conditioning" noise) that have been suggested in preliminary reports to protect the inner ear from NIHL and elucidation of the underlying mechanisms.
- Investigation into the physiologic mechanisms underlying the synergistic effects of certain drugs and noise exposure in animal models.

Conclusions and Recommendations

- Sounds of sufficient intensity and duration will damage the ear and result in temporary or permanent hearing loss at any age.
- NIHL is characterized by specific anatomic and physiologic changes in the inner ear.
- Sounds with levels less than 75 dB(A), even after long exposures, are unlikely to cause permanent hearing loss.
- Sounds with levels above 85 dB(A) with exposures of eight hours per day will produce permanent hearing loss after many years.
- There is a broad range of individual differences among people in the amount of hearing loss each suffers as a result of identical exposures.
- Current scientific knowledge is inadequate to predict that any particular individual will be safe when exposed to a hazardous noise.
- Because sources of potentially hazardous sound are present in both occupational and nonoccupational settings, personal hearing protection should be used when hazardous exposures are unavoidable.
- Vigorous enforcement of existing regulations, particularly for the workplace and consumer product labeling, would significantly reduce the risk of workplace NIHL. Regulations should be broadened to encompass all employees with hazardous noise exposures.
- Application of existing technologies for source noise control, especially in the manufacture of new equipment and construction of new facilities, would significantly reduce sound levels at the ear.
- In addition to existing hearing conservation programs, a comprehensive program of education regarding the causes and prevention of NIHL should be developed and disseminated, with specific attention directed toward educating school-age children.

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Omeprazole

GRACE CHEUNG, R.PH.

Introduction

OMEPRAZOLE (Losec®—Merck Sharp & Dohme) is a substituted benzimidazole that represents a new class of drugs approved by the FDA for gastrointestinal reflux esophagitis, symtomatic gastroesophageal reflux disease (GERD) that responds poorly to H_2antagonist therapy, and for the treatment of hypersecretory conditions.[1,2,4]

Pharmacology and pharmacokinetics

Omeprazole does not possess the same pharmacological activity as the H_2 histamine antagonists or anticholinergic agents. Instead, it irreversibly binds with the proton pump (H^+/K^+-ATPase) in the parietal cell to inhibit acid secretion. This irreversible binding may be responsible for the long duration of action observed with omeprazole.[3-6]

The dosage form of omeprazole is a delayed-release capsule and absorption occurs within 0.5 to 3.5 hours.[3,7] In healthy subjects, approximately 54% of a 20 mg dose is available in the systemic circulation and bioavailability is noted to increase with increasing dosage. This may be due to partial saturation of enzymes responsible for first pass metabolism.[2,8] Peak plasma concentration is reached within one to five hours. Omeprazole has high protein binding of approximately 95%. The drug distributes rapidly to extravascular sites after intravenous administration, however, following oral omperazole, both stomach and duodenum contain the highest drug concentrations.[2,8] Although omeprazole has an elimination half-life of between 0.5 and 1.5 hours, a single 40 mg dose has been shown to inhibit acid output by 34% and 18% after three and four days respectively.[9] Omeprazole is extensively metabolized in the liver with 77% of the administered dose eliminated in the urine as six metabolites. Although three of them have been identified in human plasma, none of them contributes to acid inhibition.[2,3]

Clinical Trials

In a randomized trial on 63 patients with ulcerative esophagitis, Dent et al confirmed the superiority of healing, 81% vs 6% with placebo, after four weeks treatment.[10] A similar study compared omeprazole 40 mg daily with ranitidine 150 mg twice a day in 61 patients. The healing rates after week four were 74% and 43% for omperazole and ranitidine respectively, and a significant number of patients on omperazole had greater relief of heartburn during therapy.[11]

Several open studies with small numbers of patients have been conducted in hypersecretory conditions, particularly in patients who were resistant to H_2 antagonist treatment.[1,12] Lamers conducted a study with seven patients for eight to 19 months in which patients received omeprazole 30 to 120mg/day. Their symptoms were relieved within two weeks and no adverse reactions were noticed during treatment.[12] Delchier reported similar results with his study in seven patients who had hypersecretory problems and were resistant to high dose H_2 antagonist treatment (167 to 200 mg/hr IV cimetidine or 600-1200 mg/day PO ranitidine). The patients received omeprazole 60 to 120 mg daily and in approximately three weeks endoscopy revealed no lesions; symptoms did not reoccur in any of the patients.[1]

Omeprazole has been shown to be effective in the treatment of reflux esophagitis. Dammann, in a double-blind study, compared omeprazole 40 mg/day with ranitidine 150 mg BID in 178 patients. After three weeks of treatment omeprazole was more effective than ranitidine in relieving symptoms. The greatest difference in improvement was seen at six weeks in which omeprazole relieved symptoms in 85% of patients compared to 67% with ranitidine.[13]

There are a number of trials demonstrating the efficacy of omeprazole for duodenal and gastric ulcers. At this time omeprazole is not approved for these indications.

Adverse reactions

Therapeutic trials show that omeprazole is well tolerated and the risk for serious or irreversible side effects is low. Most studies indicated that adverse effects are mild and transient; about 4% of the patients experience gas-

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trointestinal effects which include diarrhea, nausea, constipation, and abdominal pain.[1,2] Reports of mild CNS toxicity possibly attributable to omeprazole have been reported and include: headache, fatigue, transient dizziness, weakness, and numbness of extremities.[14,15]

In one of the first clinical trials, Gustavsson et al noted a slight increase of serum alanine aminotransferase concentrations. Since then no other clinical trials have been associated with abnormal liver function tests.[2,16] Overall the majority of studies have showed no significantly abnormal laboratory values, renal, or endocrine effects.

Data on the long-term safety of omeprazole administered are limited. Rats treated with high doses of omeprazole for two years have been reported to develop cell hyperplasia and carcinoid tumors.[3] Thus, at this time, long-term use of omeprazole should be avoided until additional data are available.

Drug interactions

Omeprazole appears to affect drugs that are metabolized by the cytochrome P-450 oxidative enzyme system. The concomitant administration of omeprazole and diazepam produced a 130% increase in mean elimination half-life and subsequent increases in plasma diazepam concentration. The clinical significance was not determined.[17]

The administration of phenytoin and omeprazole has been reported to produce a 27% increase in elimination half-life of phenytoin in healthy volunteers. Close monitoring is recommended in patients stabilized on phenytoin who are given omeprazole.[18]

Omeprazole may prolong the elimination of warfarin. However, the effects of omeprazole on the anticoagulation from warfarin appears to be minimal and the interaction is of doubtful clinical significance.[18]

Studies in which omeprazole and antacids were administered concurrently demonstrated no significant effect on omeprazole bioavailability.[19] However, there is a potential interaction on the bioavailability of certain drugs that rely on an acidic environment for gastrointestinal absorption (ie, ketoconazole, tetracycline, and ampicillin esters). Omeprazole may decrease the absorption and efficacy of these drugs, but further studies are needed to determine the clinical significance of these interactions.[1]

Dosage, administration, and cost

Omeprazole is a delayed-release capsule that should not be crushed, chewed, or opened. It should be swallowed whole and taken before meals (breakfast). For treatment of GERD and erosive esophagitis, the recommended oral dose is 20 mg daily for four to eight weeks. In hypersecretory conditions, the usual starting dose is 60 mg daily and dosage should be adjusted to the individual patient's needs.

At Hartford Hospital, omeprazole is restricted to use or approval by the gastroenterology service. Cost to the pharmacy is $2.52 per 20 mg dose.

Summary

Omeprazole is the first acid-pump inhibitor. With its unique mechanism of action, it represents a new class of drugs in treatment of GERD, reflux esophagitis, and hypersecretory conditions. Overall, its adverse effects are mild and transient and found to be well-tolerated. Thus, omeprazole will serve as an important new agent in the management of some gastrointestinal disorders.

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Adjunct Chemotherapy of Early Breast Cancer

THE MEDICAL LETTER

The most important prognostic variable in early breast cancer is axillary lymph node involvement. Based on past experience, after 10 years about 70% of node-negative patients will be alive and apparently free of disease; about 30% will have relapsed or died. Patients with positive nodes may have a 30% to 60% relapse rate, depending on the number of positive nodes and other prognostic factors, such as the presence of estrogen receptors (IC Henderson et al, in VT DeVita, Jr et al, eds, *Cancer: Principles and Practice of Oncology*, 3rd ed, Philadelphia: Lippincott, 1989, p 1197). Which of these patients should receive adjuvant treatment with cytotoxic drugs and/or endocrine therapy is controversial; a National Cancer Institute (NCI) Consensus Conference on this subject is scheduled for June.

NODE-NEGATIVE PATIENTS — One study in 90 node-negative patients with negative estrogen receptors compared a cytotoxic regimen including cyclophosphamide (*Cytoxan;* and others), methotrexate (*Folex;* and others) and fluorouracil (*Andrucil;* and others) with observation alone; after six years, six of the treated patients and 17 of the control patients had died (G Bonadonna, *J Clin Oncol,* 7:1380, 1989). Three large prospective controlled trials including a total of more than 2300 node-negative patients, mostly estrogen-receptor-negative, found that treatment with various cytotoxic drugs increased the percentage of disease-free survivors three to four years later from 69% to 84%, 71% to 80%, and 73% to 77% (EG Mansour et al, *N Engl J Med,* 320:485, 1989; B Fisher et al, *N Engl J Med,* 320:473, 1989; Ludwig Breast Cancer Study Group, *N Engl J Med,* 320:491, 1989). Another study in more than 2500 node-negative, estrogen-receptor-positive patients found that treatment with tamoxifen (*Nolvadex*), an oral antiestrogen with relatively little toxicity, increased five-year disease-free survival from 77% to 83% (B Fisher et al, *N Engl J Med,* 320:479, 1989).

All of these studies included few patients with small tumors because of difficulty in obtaining sufficient tissue to study receptors; the results of other studies have suggested that patients with tumors less than 1 cm in diameter have an excellent prognosis without any adjuvant therapy (PP Rosen et al, *J Clin Oncol,* 7:355, 1989).

NODE-POSITIVE PATIENTS — Premenopausal- Most experts agree that premenopausal patients with positive nodes should receive cytotoxic drugs, and many studies have demonstrated that combinations of drugs are more effective than single agents (Early Breast Cancer Trialists' Collaborative Group, *N Engl J Med,* 319:1681, 1988). The choice, dosage, and duration of cytotoxic drugs are controversial. Many oncologists recommend six months of cyclophosphamide, methotrexate, and fluorouracil (CMF); some substitute doxorubicin (*Adriamycin* for methotrexate (CAF). Limited data have not demonstrated increased survival in premenopausal node-positive patients treated with tamoxifen, and a negative effect has been reported when tamoxifen was used concurrently with cytotoxic drugs (B Fisher et al, *J Clin Oncol,* 4:459, 1986).

Postmenopausal - Whether postmenopausal node-positive patients should receive cytotoxic drugs is not clear. Participants in an earlier NCI Consensus Conference suggested that estrogen-receptor-positive postmenopausal patients should receive only tamoxifen, and receptor-negative patients, especially those with four or more positive axillary nodes, might benefit from cytotoxic drugs (Consensus Conference, *JAMA,* 254:3461, 1985). One three-year followup of 94 postmenopausal patients who were all estrogen-receptor-positive and a six-year followup of 463 patients including some who were estrogen-receptor-negative suggested an advantage in disease-free survival for combined chemohormonal therapy over hormonal therapy alone (A Goldhirsch and RD Gelber, in SE Salmon, ed, *Adjuvant Therapy of Cancer V,* Orlando: Grune and Stratton, 1987, p 297; CA Hubay et al, *Proc Am Soc Clin Oncol,* 5:63, 1986); a large collaborative study addressing this issue is in progress.

NEW PROGNOSTIC TESTS — Recent reports indicate that new tests may soon be available to identify breast cancer patients who may or may not require chemotherapy. The proliferative activity of the tumor, for example, measured by DNA flow cytometry, or the concentration in the tumor of cathepsin D, an estrogen-induced lysosomal protease, may prove to be independent prognostic indicators (GM Clark et al, *N Engl J Med,* 322:627, 1989; H Sigurdsson et al, *N Engl J Med,* 322:1045, Apr 12, 1990; AK Tandon et al, *N Engl J Med,* 322:297, Feb 1, 1990). Amplification of known oncogenes may help predict poor clinical outcome (AK Tandon et al, *J Clin Oncol,* 7:1120, 1989). These tests are, however, still not well standardized or widely available.

CONCLUSION — Among breast cancer patients with positive axillary lymph nodes, most clinicians now agree that premenopausal patients should receive cytotoxic drugs and postmenopausal patients with positive estrogen receptors should receive tamoxifen. Many oncologists also recommend adjuvant treatment for node-negative patients, especially those with larger tumors or other adverse prognostic indicators.

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Breath of Life

E. TREMAIN BRADLEY, M.D.

OBVIOUSLY the inhalation of oxygen and exhaling of carbon dioxide are essential to life and continuing function of the brain. So we think of breathing as being natural, spontaneous, in no need of special consideration—just so long as we keep doing it. Only do we become more aware and give it due consideration when it is impeded, as in asthma, emphysema, bronchitis, pneumonia, and during anesthesia.

The best treatment of any disease is prevention, or at least keeping the body, and each of its organs, in top-notch condition. My early experience in athletics, but mostly as a practicing general surgeon, stimulated my interest and encouraged analysis. What should our lungs do? Well, what do they really do, most of the time? A vast number of tiny chambers or alveoli admit air (we hope "fresh") and discharge it alternately, the surrounding capillaries unloading CO_2 and picking up oxygen. Yet a significant number of alveoli during normal breathing do not inflate as the ribs expand and the diaphragm descends. These alveoli remain collapsed (atelectatic), unless deep breathing is stimulated, usually by exercise. They tend to collect fluid and the surrounding circulation is diminished. Puddling and stasis lower resistance and promote infection. While under anesthesia and quiescent on the operating table, the broncho-pulmonary system tends to produce and collect fluid, often resulting in a more extensive atelectasis. Some of my patients early on had this problem. How to avoid it? and how to keep *everyone's* lungs healthy?

Teach your patient to take a deep breath through the mouth: "REACH" (not with the arms, but through the mouth) for more air, "more," "MORE" (in quick, successive jerks), "stretch—and let it go". Rest a moment and repeat, doing it *with* the patient (it's good for your lungs too!) and urging on with progressive sound effects. Having the patient do this periodically for several days prepares the lungs well, opening up those dormant alveoli and building up their resistance. Surgical patients should repeat it just prior to the operation, and again as soon after as possible. My nurses were wonderful in encouraging this, even in groggy patients. True, there are "blow bottles" and various gadgets to encourage individuals to increase the capacity and pressure inside the lung. Whether or not they actually aerate more alveoli, they are instruments which must be approached each time. So, rarely are they used more than once or twice a day. Whereas, the deep breathing just described can be done dozens of times a day with almost no interruption of other activities.

But what if there is phlegm, mucus, or other exudate in the bronchial tree, from whatever cause? A simple cough or even a series of coughs may be weak and ineffective, perhaps painful. In postoperative and trauma patients particularly, the cough can be made stronger and less painful by wrapping a bath towel or folded sheet around the chest (and in some cases the abdomen), then bunching up the ends together in a *tight* roll in front while the patient lets the breath way out. A big, deep breath will then, with this support, permit a more powerful and less painful cough. If the secretions are very tenaceous, a swallow, or two, of water tends to loosen them.

A very important aid in making the cough productive, in helping to shake lose and bring up material from the tracheobronchial tree, is a timed back blow. With the body flexed slightly forward (sitting, standing, or lying on the side), the nurse or doctor places one hand flat along the spine between the shoulder blades, gets the patient to take a really deep breath and then cough. Just at the moment of coughing—or a split second before—the fist of the other hand is thumped firmly against the back of the hand which is along the thoracic spine.

Why does this work? Wind blowing over a quiet lake finally makes waves and eventually white caps and spray. But if you throw a big rock into the lake, it makes waves and the spray blows off promptly. The vibration from the "thump" creates waves at the moment the larynx releases the air compressed in the lungs. Result: Production. One may ask, and reasonably so, if this thumping might dislodge sclerotic placques and cause trouble. Good judgement would dictate that a 125-pound, fragile, 80-year-old should not be thumped as vigorously as a strapping young 200-pound man. I can only say that while using this method routinely for over 35 years, I have never seen evidence of such ill effects.

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Principles for Graduate Medical Education

AMA COUNCIL ON MEDICAL EDUCATION

THE Council on Medical Education has responsibility for the study and evaluation of the continuum of medical education and is addressing graduate medical education (GME) with this report. The Council believes that the current system of GME, based on hospital-sponsored residencies, effectively prepares physicians for their future practice. The educational content of residency programs must respond to changes occurring now and those expected in the immediate future. The following are some changes that can affect GME:

- At present, virtually all medical school graduates complete a minimum of 3 years of residency training.
- The emphasis on health care provision has changed from largely inpatient care to a system that utilizes more ambulatory care than in the past; hospital stays are shorter; patients in hospitals tend to have more serious illness.
- Subspecialty education is receiving more emphasis.
- The need to define an appropriate balance between education and service remains.
- The appropriate supervision of residents and their duty hours have assumed greater importance.
- The length of residency training required for certification in a specialty field has increased in recent years and may continue to increase in the future.
- The research component of residency training is gaining emphasis.
- Federal funding of GME is being reduced.

As a result of concerns regarding these changes, the Council on Medical Education appointed a Task Force from its members to address the future of GME. The Task Force was composed of John E. Albers, M.D., chairman; Steven T. Clark (past student member); William E. Jacott, M.D.; Jonathan D. Klein, M.D. (current resident member); Karolyn J. Kramer, M.D. (past resident member); George T. Lukemeyer, M.D.; and Victor S. Sloan (current student member). Linda D. Lewis, M.D., served on the Task Force as a representative of the Section on Medical Schools.

In undertaking its charge, the Task Force has received assistance from the Council's Graduate Medical Education Advisory Committee and from Council members who are appointees to the Accreditation Council for Graduate Medical Education (ACGME). The Task Force has reviewed literature on GME and has studied changes in the "Special Requirements" for the accreditation of residencies in GME proposed by residency review committees.

Previous reports on GME adopted by the American Medical Association (AMA) House of Delegates should be noted. These include Council on Medical Education Report C (1987 Interim Meeting), "Resident Physician Working Hours and Supervision," and Board of Trustees Report D (1985 Interim Meeting), "Report of the Ad Hoc Panel on the Funding of Graduate Medical Education." The Council on Medical Education and the AMA Council on Long Range Planning and Development, with the cooperation of the AMA Resident Physicians Section, have developed a report, "The Future of Graduate Medical Education: Implications of the Changing Environment of Medicine."

Background

Early in this century, the Council issued statements that graduation from a medical school was not an adequate preparation for the practice of medicine. Since that time, and in particular since the recognition of family practice as a specialty in 1969, nearly all medical school graduates have completed a defined program of GME in preparation for practice.

On a national level, GME is controlled by ACGME requirements for the accreditation of residency programs and by medical specialty board requirements for the certification of individual physicians.

Members of the Council on Medical Education at the time this report was written were as follows: J. Lee Dockery, M.D., Chairman; William J. Reals, M.D., Vice Chairman; John E. Albers, M.D.; William E. Jacott, M.D.; Jonathan D. Klein, M.D.; George T. Lukemeyer, M.D.; Sam A. Nixon, M.D.; Frank A. Riddick, Jr, M.D.; F. Douglas Scutchfield, M.D.; Charles D. Sherman, Jr, M.D.; Victor S. Sloan; Hugh E. Stephenson, Jr, M.D.; and Richard L. Egan, M.D., Secretary, Arthur M. Osteen, Ph.D., was the Staff Author.

From the Council on Medical Education, American Medical Association, Chicago, Ill.

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Residency programs are accredited by the ACGME, whose members include four representatives from each of the following member organizations: the Association of American Medical Colleges, the American Board of Medical Specialities, the American Hospital Association, the AMA, and the Council of Medical Specialty Societies. The ACGME membership also includes a public representative and a resident physician representative. The standards, or general requirements, which must be met by all residency programs as condition for accreditation, are adopted by the ACGME, subject to approval by each of the five member organizations. The ACGME has delegated accrediting authority to each of the 24 residency review committees (RRCs). The Council is a sponsor of each of the RRCs, as is the corresponding specialty board. Nineteen of the RRCs are also sponsored by a medical specialty society. Eight of the 24 RRCs include a resident physician as an additional member. "Special Requirements" for the accreditation of residency programs under the purview of an RRC are proposed by the RRC and, after review and comment by each of the sponsors of the RRC, are approved by the ACGME.

Each of the medical specialty boards is incorporated and has final authority to elect its members. Each board determines the requirements, including the duration of required GME, for the certification of individual physicians.

Principles

The Council recommends adoption of the following principles:

***Principle** 1. Purpose of GME*

The purpose of GME is to provide a medical school graduate with the knowledge, skills, and attitudes necessary to become a competent practitioner in a recognized medical specialty.

The primary purpose of residency training is to prepare medical graduates for the clinical practice of a medical specialty. This principle is important for the validation of accreditation requirements and for the content and structure of GME.

Principle 2. Resident Physicians Planning Academic and Research Careers

Resident physicians pursuing an academic career or a career in research should complete residency training and acquire additional qualifications relating to their academic and research interests.

Some residency review committees have proposed that requirements for the accreditation of residency programs require that the resident physician actively participate in research activities. The participant in GME should develop an appreciation of scholarship, but the requirements, structure, and content of GME should be directed to preparing physicians to practice a medical specialty. Individual educational opportunities beyond the residency program should be provided for physicians who have an interest in, and show an aptitude for, academic and research pursuits.

Principle 3. Scholarly Activities

Resident physicians who are not planning careers in teaching or research should appreciate the importance of scholarly activity and should be knowledgeable in the scientific method.

The importance of scholarly activity and knowledge of the scientific method cannot be overemphasized. Current medical practice is increasingly dependent on an understanding of, and application of, the basic medical sciences. The resident physician must learn to critically review medical literature to seek and evaluate new information.

Principle 4. Institutional Responsibility for Programs

Specialty-specific GME must operate under a system of institutional governance responsible for the development and implementation of policies regarding the following: the initial authorization of programs, the appointment of program directors, funding, compliance with the Essentials of Accredited Residencies in Graduate Medical Education, *the advancement and disciplining of resident physicians, the maintenance of permanent records, and the credentialing of resident physicians who successfully complete the program.*

The residency program director has primary responsibility for the success of a residency program. However, many critical dimensions of GME require institutional resources and reliance on institutional policies.

Institutional responsibility should be exercised through an institutional committee that defines and monitors the commitment of institutional resources and services, the effectiveness of program directors and teaching staffs, the performance of individual resident physicians, and the overall effectiveness of the institution's GME programs. Governance should be accomplished through committees that include physicians with knowledge of their specialty and of GME. Resident physicians should be included in these committees.

Principle 5. Relation of Accreditation to the Purpose of Residency Training

Accreditation requirements should relate to the stated purpose of a residency program and to the knowledge, skills, and attitudes a resident physician should have on completing training.

Accreditation is a process to ensure the basic quality of an educational program. Since early in this century, the Council has fostered accreditation as a means of maintaining and improving the quality of medical education. The process consists of defining the standards for an acceptable educational program and granting accreditation when there is substantial compliance with the standards. Accreditation of a residency program assures the resident physician of access to an acceptable educational experience and assures society that those who have completed the program are prepared to practice a specialty. The purpose, or expected outcome, of GME must be defined for each specialty if the standards for accreditation are to be valid and reliable.

Principle 6. Length of Training

The usual duration of an accredited residency in a specialty should be defined in the "Special Requirements." The duration should be sufficient to achieve the stated purpose of education for a particular specialty. The time required for an individual resident physician's education may be modified depending on the aptitude of the resident physician and the availability of required clinical experiences.

The "Special Requirements for Accredited Residency Programs" specify the number of years of training needed to meet the objectives of the specialty field. In addition, and separately, individual medical specialty boards define the minimum length of participation in a residency program required for certification. A trend to lengthen the required duration of residency training has been noted. Some increases have been justified by the increasingly complex requirements for the effective practice of the specialty. In other instances, specialty boards have increased the period of time required for specialty board certification. In some instances, the required duration of residencies has been lengthened with the requirement that the resident physician engage in research activities. In other instances, specialty boards have increased the period of time required for specialty board certification. In these circumstances, program directors have agreed that residents can lengthen their training to meet requirements for certification, and, eventually, residency review committees have officially lengthened the time required for programs.

There should be wide participation in discussions concerning the appropriate educational objectives for specialty training in given fields, and these objectives, once established, should serve as the basis for determining the required length of a residency training program.

Residency training should be lengthened only after widespread agreement that the achievement of educational objectives requires a longer period of time.

Principle 7. Structured GME

Graduate medical education must include a structural formal educational component in addition to supervised clinical experience. Assignment of clinical responsibility to resident physicians must permit time for the acquisition of knowledge of the basic mechanisms and clinical pathophysiology related to the specialty. Service should not be of such intensity and duration as to comprise the educational component of GME.

The primary characteristic of GME is that it is practical and supervised. Graduate medical education is not exclusively practical, however, and resident physicians must have time to develop the habits of scholarship referred to in a separate principle.

Principle 8. Innovation in GME

The requirements for accreditation of residency training should encourage educational innovation.

Accreditation and certification as applied to GME have each evolved so as to perfect the requirements for these activities. The result has been to standardize residency programs regarding length, content, and the environment of education for each of the specialities. The detailed nature of the standards may, in fact, inhibit innovation. In contrast, the development of numerous new medical schools during the 1960s and 1970s, and curricular developments within existing medical schools, fostered experimentation and change in the education of medical students. Experiments in GME have been much less frequent. It would be appropriate to encourage controlled experiments directed toward improving the effectiveness of GME.

Principle 9. The Number of Programs Needed for Critical Mass

In most instances, institutions should offer more than one residency program, but a single well-structured program within an institution can provide quality education.

The Council's review of "Special Requirements for Accredited Residency Programs" reveals varying approaches to requirements for synergistic relationships among residency programs within a single institution. Respected authorities have reasoned that the existence of several accredited programs within an institution provides a resident physician with daily contact with resident physicians from other specialities and that this contributes to a broad understanding of medicine. In the absence of other residency programs, both formal and informal consultations can be arranged for residents with practitioners in other specialities. At the same time, a universal requirement for either the number of residency programs or for specified residency programs within the institution may be unduly restrictive.

Accreditation requirements should not prevent the existence of excellent programs in small institutions.

Principle 10. Education in the Broad Field of Medicine

The first year of GME should provide the resident physician with a broad clinical experience.

The first recommendation of the Council's Report B (1982 Annual Meeting), "Future Directions for Medical Education," stated, "The medical profession and those responsible for medical education should strengthen the general or broad component of both undergraduate and graduate medical education. All medical students and resident physicians should have a general knowledge of the whole field of medicine regardless of their projected choice of specialty." This recommendation was based on the conviction that a reasonable knowledge of the broad field of medicine is necessary if the physician is to analyze and synthesize information and to recognize clinical problems that are external to the specialty discipline. Recommendation 20 of Report B states that physicians entering residencies for specialties other than internal medicine, obstetrics-gynecology, pediatrics, general surgery, or family practice should complete a first year of residency in one of these specialties or in a transitional year program. Implementation of this recommendation has been compromised by a lack of available positions in these five specialties for resident physicians who plan to enter other specialties. The Council reaffirms Recommendation 20 of Report B.

Principle 11. Faculty Scholarship

All medical school and residency faculty members should be engaged in scholarly activities and involved in scientific inquiry.

The teaching staff of GME must provide an example for resident physicians. Scholarship may be evidenced by participation in laboratory research. Clinicians, concentrating their efforts on the care of patients, will also provide an example of scholarship by their critical knowledge of developments in their field of practice as applied to the care of their patients.

Principle 12. Requirements for Specialty Board Certification

Speciality board certification should serve to confirm the competency of a resident physician as evaluated by the program director and faculty of a residency training program. Specialty boards should accept the satisfactory completion of an accredited residency program as meeting the educational component of the requirements for certification.

The appropriate supervision of resident physicians requires a continuing evaluation of the resident physician's progress, as well as the appropriate delegation of responsibility by the program director and the teaching staff. This continuing evaluation should document the resident physician's abilities over the course of residency training.

In the past, there have been instances when specialty boards have required a longer period of residency for certification than the ACGME has required for accreditation of residency training programs in a specialty field. The comment supporting Principle 6 also applies to this Principle.

Principle 13. GME in the Ambulatory Setting

Graduate medical education should include supervised experience in ambulatory settings in addition to the traditional inpatient experience.

Medical care is increasingly provided in ambulatory settings. This trend may curtail the availability of inpatients for the traditional teaching of resident physicians. At least part of the educational program that involves patient care should be in ambulatory settings, because this is where the clinical experience is increasingly available and where future specialists may encounter a significant part of their practice.

Principle 14. Verification of Resident Physician Experience

The program director should document, and a record should be maintained within the institution, of a resident physician's specific experiences and the knowledge, skills, and attitudes demonstrated.

Physicians are increasingly required to document their qualifications for clinical practice. Documentation is necessary when the physician requests hospital privileges. It is, therefore, important that these evaluations be completed accurately, and that they become a part of the permanent record maintained within the institution sponsoring the residency program.

Principle 15. Supervision of Resident Physicians

Program directors must supervise the clinical performance of resident physicians. The policies of the sponsoring institution, as enforced by the program director, must ensure that the clinical activities of each resident physician are supervised to a degree that reflects the ability of the resident physician.

The supervision of resident physicians in conformity with institutional policies is the responsibility of the program director and the teaching staff. This supervision must recognize the necessity of the resident physician having increasing responsibility consistent with his or her knowledge, technical ability, and clinical judgement. This supervision must also ensure the interests of the patient are protected.

Principle 16. Compensation of Resident Physicians

All residents should be compensated. Residents should receive fringe benefits, including, but not limited to, health, disability, and professional liability insurance and should have access to other benefits offered by the institution. Residents must be informed of fringe benefits and of their access to them.

Resident physicians benefit by participating in GME and simultaneously provide a significant amount of service to patients. The value of this service justifies a level of compensation that should relate to the value of these services. Unless there is clear justification, institutions should maintain a compensation schedule so that resident physicians serving in different programs within the institution, at similar levels, receive equal compensation.

Reported instances of resident physicians serving without compensation are not in the best interests of the GME or the individual resident physician. With rare exceptions, resident physicians do not have extensive financial resources, and often have large debt burdens, which makes it difficult to pursue a residency effectively in the absence of a salary.

Conclusion

Graduate medical education is in the process of change. Factors external to the educational programs are expected to lead to further change in the near future. The implementation of these principles can serve to protect and enhance the excellence of GME provided to resident physicians in US medical institutions.

Recommendation

The Council on Medical Education recommends that these principles be adopted by the House of Delegates and that the AMA urge the ACGME to incorporate these principles in the body of the revised "General Requirements" of the *Essentials of Accredited Residencies of Graduate Medical Education.*

Will Your Pension Plan Assets Survive Bankruptcy?

PAUL L. BEHLING, ESQ. AND KAREN L. CLUTE, ESQ.

Introduction

INCREASING professional liability claims and recent bankruptcy filings by prominent individuals and corporations have focused renewed attention on the security of pension plans and other benefit packages. Most people do not realize that much of the law in this area has not yet been fully developed. This uncertainty (coupled with the dearth of reported judicial decisions) makes it especially difficult to predict the effects of a bankruptcy filing on a qualified employee benefit plan. This article will focus on the particularly problematic situation where an owner-participant in a qualified pension plan ends up in personal bankruptcy.[1] It may come as a very unpleasant surprise to many such owner-participants in Connecticut to realize that their retirement benefits may be less secure from creditors in the event of a bankruptcy than if they worked for, and had retirement benefits through, a large or public company.

In 1974, when Congress passed the Employees' Retirement Income Security Act (ERISA), one of its primary objectives was to establish a uniform federal system to regulate private pensions and provide greater security to plan participants. Since that time, statutory provisions, regulations and rulings promulgated by the Department of Labor and the Internal Revenue Service, have created elaborate mechanisms for safeguarding plan investments and making pension plan benefits available to greater numbers of people. But amidst the complex mandatory compliance obligations, it is possible to become overly complacent, trusting that assets which have been set aside to provide future benefits will, in fact, be available to provide those benefits. At present, that may or may not be true for small plans or plans sponsored by a self-employed individual. Because of the interplay of ERISA (and parallel tax code provisions) and the federal Bankruptcy Code (and related state trust law), owner-participants may find under certain circumstances that their plan assets will be involuntarily transferred to a bankruptcy court trustee for use in satisfying the claims of creditors. This may result not only in the loss of the owner-participant's plan assets, but may also disqualify the entire plan if assets are actually transferred out of the plan's trust to a third party. If the plan is disqualified, tax deductions for the plan sponsor (ie, the employer) will be disallowed and *all* plan participants will be taxed on the value of their vested benefits.

How the Problem May Arise

In order to be "qualified," a pension plan must comply with ERISA and certain provisions of the tax code. If a pension plan is qualified, the plan sponsor may deduct its contributions to the plan, the participant does not have to include the contributions made on his or her behalf in current taxable income, and earnings on the contributions may accumulate on a tax deferred basis, thereby increasing the amount of assets available to provide retirement income and other benefits.

All qualified pension plans must contain a so-called "antialienation" clause. This clause prohibits the assignment, attachment, garnishment, anticipation, or other transfer of assets held on behalf of a participant by a pension plan. Thus, as a general rule, creditors may not reach plan assets to satisfy debts of a plan participant or beneficiary. (A statutory exception to this general rule has been carved out for spousal awards pursuant to certain court ordered Qualified Domestic Relations Orders.)

Despite the general objectives of ERISA, the rule regarding the nonalienability of pension plan assets may break down if the authority of a federal Bankruptcy Court is invoked. Under the federal Bankruptcy Code, a debtor may either voluntarily seek the protection of the bankruptcy court or may be involuntarily placed there by the actions of creditors. Once a bankruptcy case is filed, the debtor's assets will be marshalled into a "bankruptcy estate" and a plan will be devised to satisfy the claims of the debtor's creditors. Thus, one of the first tasks in a bankruptcy case is to determine what assets of the debtor shall constitute the bankruptcy estate. In

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[1] Although this article addresses only pension plans, much of the discussion is equally applicable to all qualified plans except individual retirement accounts (IRAs).

PAUL L. BEHLING, ESQ., Partner; KAREN L. CLUTE, ESQ., Associate; both with Wiggin & Dana, New Haven and Hartford.

general, all of a debtor's assets are part of the bankruptcy estate, unless (1) excluded from the estate under §541 of the Bankruptcy Code or (2) exempted out of the estate under §522 of the Bankruptcy Code.

Exclusions from the Estate

Subsection (c) of §541 of the Bankruptcy Code states: "A restriction on the transfer of a beneficial interest of the debtor in a trust that is enforceable under applicable nonbankruptcy law is enforceable in a [bankruptcy] case." Since the assets of a qualified pension plan must be held in a trust and the required antialienation clause is a "restriction on the transfer of a beneficial interest of the debtor," the issue becomes whether the antialienation clause is "enforceable under applicable nonbankruptcy law." Although one might be tempted to argue that ERISA itself must be an "applicable nonbankruptcy law," in fact, the majority (but not all) of the courts which have faced this issue have rejected that position. Instead, "enforceable under applicable nonbankruptcy law" has been judicially interpreted to mean enforceable under the state's trust law.

Under the common law[2] of trusts, a trust with an antialienation provision like that required by ERISA is generally known as a "spendthrift trust." Historically, it was thought that the grantor (or "settlor") of a trust should be able to set aside assets for the support of a given person without fear that that individual, through mismanagement, incompetence, or profligacy, would squander away the long-term benefits of the trust. In other words, the law protected the interest of the grantor who wished to provide for the welfare of an individual, rather than the interests of that individual's creditors.

The preferential treatment in enforcing the intentions of the grantor over the claims of a beneficiary's creditors is almost always subject to one important exception: the common law has consistently refused to enforce a spendthrift trust if the grantor of the trust is also a beneficiary of the trust. Trusts in which a grantor is also a beneficiary are known as "self-settled" trusts.

On the whole, this prohibition against enforcing "self-settled" trusts is salutary; otherwise, everyone would put their money into a spendthrift trust, name themselves as the sole beneficiary, and thwart the interests of their creditors. However, when this rule is applied to ERISA pension plans, some unexpected results can occur. Unincorporated professionals are at the greatest risk of losing their retirement benefits, but even shareholders of small corporations can be at substantial risk. For example, consider the situation of a doctor who is the sole shareholder of a professional corporation (P.C.). Although technically the P.C. will be the plan sponsor and the grantor of the trust which holds the assets of the P.C.'s pension plan, in many cases the law will look past the formal distinction between the P.C. and the individual doctor and will determine that the doctor is in fact the grantor of the trust. This will be particularly true when the doctor, even if acting on behalf of the P.C. or as a trustee, has the power to amend or terminate the pension plan or to direct the investment of the plan assets, or in other ways has retained a significant amount of control over the trust. In this situation, with respect to that doctor's own pension benefits under the plan (ie, as a participant), the trust is likely to be deemed to be "self-settled" and not enforceable under applicable state law as a valid spendthrift trust. As such, the doctor's share of the plan assets will not be excluded from the bankruptcy estate.

The situation in Connecticut is slightly more complicated. Connecticut does not recognize the common law spendthrift trust, but §52-321 of the Connecticut General Statutes provides for a type of trust which can serve many of the same purposes. For this reason §52-321 is often referred to as the state "spendthrift trust statute," and trusts which satisfy the requirements of §52-321 are often referred to as "spendthrift trusts," even though they do not conform to the common law definition. Like the common law, the statute allows the grantor of the trust to set aside for the support of a beneficiary assets that may not be attached, garnisheed, or otherwise made available to a creditor. However, the statute also requires that the trustee of the trust have the discretion to accumulate assets and to withhold income from the beneficiary. Furthermore, if the trust "has been expressly provided to be for the support of the beneficiary or his family, a court...may make such order regarding the surplus, if any, not required for the support of the beneficiary or his family, as justice and equity may require." In other words, a court may order that the so-called "corpus" of a §52-321 trust may be invaded if there are assets there which are not necessary for the support of the beneficiary. Presumably, if there are trust assets available which are not necessary for the support of the beneficiary, most courts, as a matter of justice and equity, would allow those assets to be used to satisfy the claims of legitimate creditors. This, in turn, means that because Connecticut does not recognize common law spendthrift trusts, and because Connecticut's so-called "spendthrift trust statute" in fact allows courts to transfer assets of the trust to unrelated third parties, for purposes of §541 of the Bankruptcy Code, in Connecticut there may be no "applicable nonbankruptcy law" which will enforce the antialienation clause of a qualified pension plan. As a result, because the requirements for exclusion under §541 of the Bankruptcy Code cannot be met, the debtor's share of the assets held by a pension plan may be included in the debtor's bankruptcy estate.

Exemptions from the Estate

Inclusion in the bankruptcy estate is not, in and of itself, tantamount to a transfer of assets for the benefit of the debtor's creditors. Certain assets may still be exempted out of the estate if the requirements of §522 of the

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[2] The common law is the law as it has developed through judicial decisions. The common law may be superceded by statutory law, which is law enacted by legislatures.

Bankruptcy Code are met. Section 522 allows the debtor to elect either the federal exemption scheme or the exemptions provided by the state law of the debtor.

Under the federal scheme, the debtor's "right to receive...a payment" from an ERISA qualified plan may be exempted out of the bankruptcy estate "to the extent reasonably necessary for the support of the debtor and any dependent of the debtor." While it seems clear that in order to have a right to receive payments in the future, it is usually necessary to protect plan assets in the present; not all courts have agreed with this position. Furthermore, the qualifier "to the extent reasonably necessary" creates a minefield of uncertainty for the debtor.

Courts in other states which have faced this issue have indicated that in considering what is "reasonably necessary" they will examine the debtor's present and anticipated living expenses; the debtor's skills, training, and ability to work, and the present and anticipated income therefrom; the age and health of the debtor and the debtor's dependents; the debtor's other assets and their liquidity; the debtor's other financial obligations; and any other special needs. Such an examination would no doubt involve an unpleasant inquiry into the debtor's private life, but, more importantly, the factual nature of the inquiry makes each situation unique and the outcome unpredictable.

The state exemptions in Connecticut are similarly qualified. Under §52-352b(m) of the Connecticut General Statutes, "payments received" under a qualified pension plan can be exempted out of a bankruptcy estate, "but only to the extent that wages are exempt... ." At least two significant issues are raised by this statutory language. First, the Connecticut statute only addresses "payments received"; the statute is silent as to the treatment of assets which are held by a plan on behalf of a debtor before that debtor has become eligible to receive payments. In other states, some courts which have faced this type of issue have reasoned that, in order to receive payments, there must be preexisting assets. However, in the absence of explicit direction from the state legislature, there is no guarantee that Bankruptcy Courts in Connecticut will interpret the Connecticut statute similarly. As such, a debtor who has not yet reached retirement age or who is not disabled could be denied the right to exempt any pension plan assets out of the bankruptcy estate. Second, even if the debtor is in so-called "pay status" and currently receiving benefits, the amount by which the debtor's benefit payments exceed the state limits for garnisheeing wages will be not be exempted out of the bankruptcy estate, but will be subject to the claims of creditors.[3]

What Can Be Done to Mitigate the Effects of the Problem?

Unfortunately, because of the unsettled state of the law, there are no surefire ways for Connecticut owner-participants to forestall the risk of possible Bankruptcy Court action against their pension plan assets. Perhaps even more frustrating, there are no surefire ways for co-owners (or for that matter, employees) to ensure that the personal bankruptcy of a co-owner will not jeopardize one's own tax advantages.[4] Some commentators have suggested structuring the plan and trust agreement so as to remove as much as possible the owner-participant's control over the plan and the trust assets. While desirable, this, in itself, will not guarantee exclusion or exemption from the bankruptcy estate and will not bring an ERISA plan within the Connecticut "spendthrift trust" statute. It may also entail unwanted administrative complications and expenses because of the necessary involvement of third parties.

In light of this rather grim prognosis, several states have recently enacted legislation specifically aimed at protecting qualified plan assets from the reach of bankruptcy creditors. For example, New York amended its trusts and estates law to provide that trusts created in connection with ERISA qualified plans shall not be deemed to be self-settled. Once that hurdle is removed, ERISA qualified trusts, with their required antialienation clauses, are valid spendthrift trusts under New York law and can be excluded from a bankruptcy estate. Florida has taken a different approach. It amended its state exemption scheme to provide that "any money or other assets payable to a participant or beneficiary from, or any interest of any participant or beneficiary in, a [qualified] retirement or profit sharing plan...is exempt from all claims of creditors of the beneficiary or participant."

The authors have been active in attempts to have protective legislation proposed before the Connecticut General Assembly, and are also involved in a project of the American Bar Association studying possible federal legislative solutions for recommendation to Congress. However, until either new federal or state legislation is passed, Connecticut owner-partcipants have ample cause for concern.

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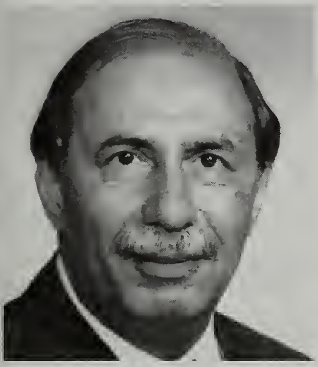
[3] Roughly speaking, the lesser of 1) the amount by which the debtor's income exceeds 40 times the minimum wage or 2) 25% of the debtor's "disposable earnings" is subject to garnishment. The debtor's "disposable earnings" is a factual determination based upon the individual's unique financial and family situation.

[4] While the bankruptcy of a co-owner may result in the transfer of assets from the plan to a third party creditor, unrelated plan participants need not be concerned about the safety of their own plan benefits; only the assets allocable to the participant in bankruptcy can be transferred. However, the fact of the third party transfer may result in the disqualification of the plan, which, in turn, will increase the taxable income of all plan participants and will result in the disallowance of certain tax deductions by the plan sponsor.

1990 Legislative Session



The 1990 General Assembly has adjourned for another year. CSMS monitors more than a hundred issues that affect the practice of medicine. And, during the session we confronted a number of issues that had surfaced in prior years. For example, medicare assignment, direct access for physical therapists, and triplicate prescription forms. Overall, we fared relatively well during this session.

Many physicians were active in our efforts this year and I would like to extend my thanks to them for that activism—it truly helps. Contacting legislators and expressing your views on important issues is the key to ensuring medicine's success at the Capitol.

This November we will elect a governor and all 187 members of the House of Representatives and Senate. Following the elections, there will be a long legislative session. CSMS will be developing its legislative program over the summer and early fall in preparation for these events. Please plan to participate in this process and to work closely with the Society in the coming year.

The following are highlights of what happened this past session:

Medicare assignment - Initially the AARP discussed with us the possibility of across-the-board mandatory assignment since our neighboring state of Rhode Island just implemented such a law and Massachusetts physicians had already lost a similar battle. We made it quite clear that this was a totally unacceptable proposal to us, and in fact there was no compromise on mandatory assignment that we would accept. Failing to secure enough support for the whole package, the AARP proposed raising the income eligibility level by 25%. This proposal narrowly (11-9) passed through committee and again narrowly (74-71) prevailed in the House of Representatives. Eventually, the income eligibility requirements were increased only 15% instead of the requested 25%. This increases the mandatory medicare assignment threshold from $20,700 to $22,770 for a single person and from $24,900 to $27,390 for a married couple.

Direct access for physical therapists - For the fourth year, the physical therapists attempted to gain direct access to patients. However, this bill died on a 22-18 vote in the Appropriations Committee.

Changing the law concerning epileptic drivers - Until this year, physicians were required to report epileptic patients to the Department of Motor Vehicles. This had caused problems for physicians and patients alike. The new law requires patients with chronic health problems to report themselves to the DMV. A physician may report a patient with chronic health problems to DMV with no fear of reprisals.

Regulation of Utilization Review Agents - A bill passed that requires the insurance commissioner to study ways to regulate private utilization review agents.

Triplicate Prescription Forms - Once again, the Department of Consumer Protection attempted to pass a bill, requiring triplicate prescription forms be used for certain schedules of drugs. The bill died in committee.

State Blue Ribbon Commission on Health Insurance - Legislation was passed which will bring immediate relief (July 1) to 60,000 of the state's 272,000 uninsured. Special, lower-cost health insurance policies will be made available to 60,000 of the 250,000 employees of small firms that have no coverage. In addition, Medicaid eligibility is being expanded to include certain uncovered pregnant women, families with children, disabled people, and some elderly who do not now qualify for welfare benefits. Although much remains to be done, a start has been made on the job of reducing the numbers of the uninsured.

Mehdi S. Eslami, M.D.
President

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Curiosity: An Aperitif

ROBERT U. MASSEY, M.D.

BEFORE beginning a lecture or seminar in the history of medicine I feel an unpleasantness rising in the back of my neck; I have an inkling that most of the students are wondering why we waste their time in this way. So I stumble around with the question that my imagination has put into their heads: why bother about history? We have a CD-ROM in the library with the last five years of medical literature compressed onto it. Who needs more?

My answers, offered before they think to ask, vary, but generally include:

1. Curiosity, the same reason most of us would like to see Leningrad or poke around on the Martian desert.
2. To know ourselves better, especially our limits.
3. To understand the present better by giving it a third and maybe a fourth dimension.
4. And then I remind them that when we speak of dementia we first describe memory loss, and that tyrants are generally intent upon rewriting history, or eliminating it, which comes to the same thing.

It seems to me that teachers are apt to pay too little attention to curiosity; they would like us to have a higher, more intellectual, or at least practical reason to learn whatever it is they have been assigned to teach us. Most small mammals that I have had a chance to watch—dogs, cats, chipmunks, squirrels—are intensely curious, more interested in the world around them than they are even in food or sex; their lives would be shorter if they were not so inquisitive. Maybe our own native, burning curiosity has been dampened by living in a world that is too safe, and by having been told too often not to ask so many questions.

To medical students medicine is symbolized by its technology: the hypodermic needle, the stethoscope, the microscope, the ophthalmoscope (I recall my wonder at being able to see inside the eyeball!), the x-ray, and all the paraphernalia of surgery. The economics of health care, the sociology of disease, even medical biography are acquired tastes for most, but no one passes a display case filled with saws and amputation knives neatly packed in their felt-lined boxes without a shudder and a hundred questions.

Then to discover that not only our colonial forebears used these things, but even the Romans, the Greeks, and long before them the Egyptians and their eastern neighbors in the valley between the rivers, will fire the fertile imaginations of those just beginning to think about the application of steel to living flesh. "What did they do about pain?" What indeed! In Celsus' *De Medicina*, written before the New Testament, we read about how to repair an inguinal hernia:

> . . . and for the day before he must abstain from food; . . . he must lie on his back; next if the groin has to be cut into, and if the pubes is already covered with hair, this is to be shaved off beforehand: and then after stretching the scrotum, so that the skin of the groin is rendered tense, the cut is made below the abdominal cavity, where the membranes below are continuous with the abdominal wall. Now the laying open is to be done boldly (audacter), until the outer tunic. . . is cut through, and the middle tunic reached. When an incision has been made, an opening presents leading deeper. Into this the index finger of the left hand is introduced, in order that by the separation of the intervening little membranes the hernial sac may be freed. . . .

The account goes on in clear, simple Latin sentences, including instructions to take care "lest the abdominal membrane be injured and set up inflammation." There is an admonition to tie the blood vessels, leaving the threads to hang out of the wound, and finally, "Through the margins of the wound itself two pins (fibulae) are then passed, and over this an agglutinating dressing."[1]

Do they picture in their mind's eye this first-century craftsman, this *chirurgus*, slowly working his way through the confusing structures of the groin, repairing an inguinal hernia in a conscious patient, "with a strong and steady hand which never trembles, . . . filled with pity, so that he wishes to cure his patient, yet is not moved by his cries. . . ."[2]

How much of Imperial Rome's GNP was spent on health care might interest some, but not a 22-year-old medical student! "Tell me, what did they do about the pain?"

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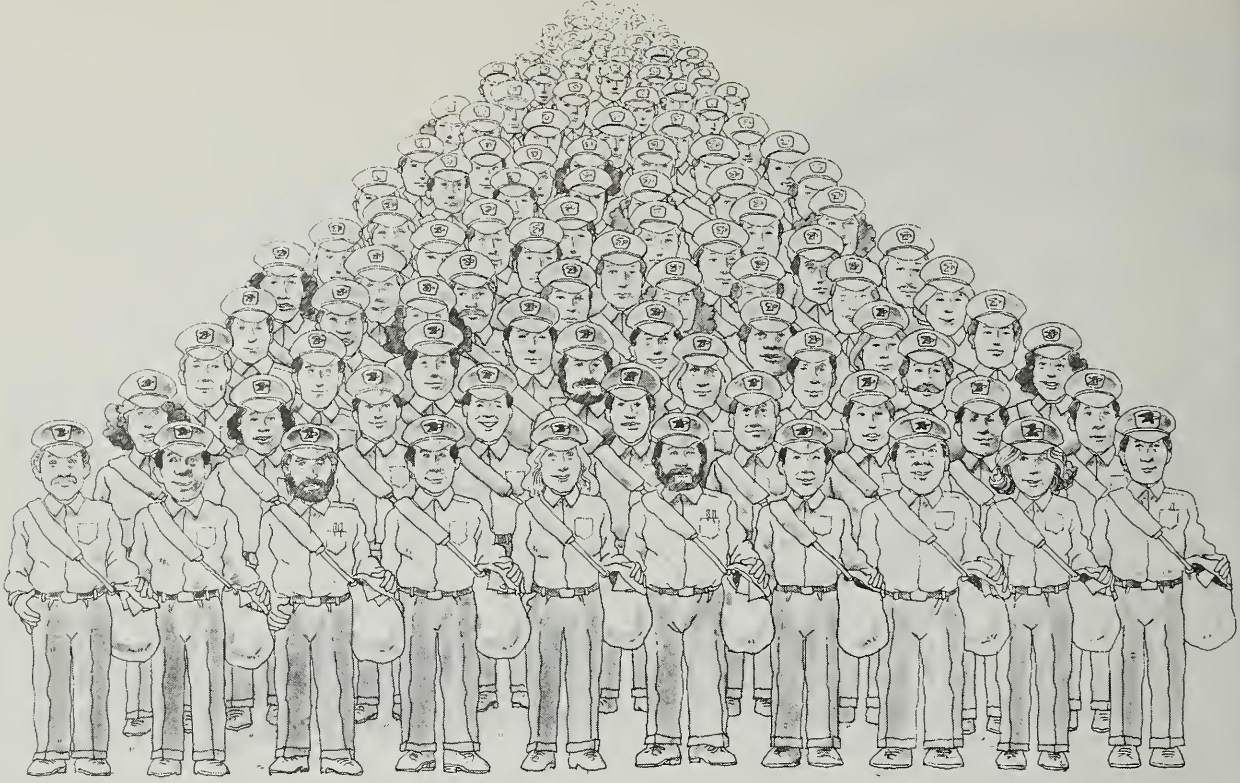

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A Busy Six Months

JOSEPH M. HEALEY

WE seem as a society unable to escape the absence of consensus about public policy at the "edges of life." The questions of abortion and decisions at the end of life continue to occupy central roles in public and professional discussions. Already 1990 has been a busy year for these issues. During the past six months, the United States Supreme Court has decided two major cases dealing with abortion and one dealing with the withdrawal of artificial nutrition and hydration from a patient in a persistent vegetative state. The Connecticut legislature has passed one statute dealing with abortion and another with using a power of attorney to make health care decisions. Unfortunately, the results of this activity have been mixed. Much of what has occurred may well have only added to the confusion and dissatisfaction which abounds in these controversial areas.

The good news is that the Connecticut legislature was able to clarify Connecticut law governing abortion and to bring it into conformity with existing federal case law. A second source of good news was the conclusion of a majority of the justices of the United States Supreme Court that there is a constitutionally protected right to refuse treatment including artificial nutrition and hydration. The bad news is that the relief sought in the name of Nancy Cruzan was not granted and her tragic situation continues. Furthermore, both the Cruzan case and the Connecticut power of attorney statute raise questions about the role of family members in health care decisions for their incompetent relatives. These various cases and statutes will be subjects of this column and the next several columns.

The Connecticut abortion statute[1] has four major sections which (1) repealed the previous Connecticut statutes dealing with abortion; (2) established that the decision to terminate a pregnancy prior to fetal viability was solely that of the woman in consultation with her physician; (3) prohibited the performance of abortion after fetal viability unless necessary to preserve the life or health of the woman; and (4) required the provision and documentation of pregnancy information and counseling before the performance of abortion upon a minor.

The repealed provisions had been declared unconstitutional in 1973 and their enforcement had been permanently enjoined.[2] Nonetheless, they had never been removed from the General Statutes. Among the repealed provisions were criminal sanctions for attempting to provide or procure a miscarriage or abortion unless such procedure were necessary to preserve the life of the woman or her fetus. The new sections recognizing the rights of the woman and her physician to decide to terminate a pregnancy before fetal viability or when necessary to preserve the life or health of the woman embody the legal principles established in *Roe v. Wade* [3] and *Doe v. Bolton*[4] and affirmed in subsequent cases during the past seventeen years. The longest sections of the new act describe the information which must be disclosed to a minor before consent can be obtained. These sections and the recent United States Supreme Court decisions dealing with minors, parents, and abortion will be the subjects of next month's column.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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50 Years Ago

From the Journal of the Connecticut State Medical Society
July 1940

Modern Treatment of Pneumonia*

THEODORE S. EVANS, M.D.,
New Haven, Conn.

THE conquest of pneumonia by the biologist and the experimental chemist was protracted and filled with pitfalls. Digitalis was formerly used a panacea. This was followed by the use of concentrated glucose intravenously still of value along with blood transfusions as an adjunct to specific therapy. Physio-therapy (Diathermy) was employed by many but was expensive and gave little evidence of altering the course of the disease. Doctor F. G. Blake and his associates at Yale Medical School revived the use of pneumo-thorax in patients who did not fall into the serum specific groups. This proved to be but a method of symptomatic therapy for the relief of pleural pain and did not cure the infection or reduce the mortality.

As early as 1922 serum for group I pneumonia was used, in large quantities at first because of its low potency. At the Grace Hospital in 1938 the first concerted effort was made to use serum in all possible cases and to use sulphanilamide where there was a clear cut indication. In 1939 pyridine sulphanilamide, furnished by Merck & Co., was used in nearly all cases of pneumonia at Grace Hospital in order to test its efficiency. Serum was still used in certain cases as was plain sulphanilamide.

Results of Treatment

The results of our experience afford no general conclusions as the number of cases is small but in general our results are similar to those of others who have worked under similar conditions. From 1933 to 1937, inclusive, before the use of serum or sulphanilamide the death rate was approximately 33%. In 1938 with serum the death rate dropped to 11%. In 1939 with serum, sulphanilamide and pyridine sulphanilamide death rate fell to 5%. The reductions in mortality for the past two years are apparently due to these agents in large measure.

In 1938 there were no deaths among 11 cases of lobar pneumonia treated with serum and but one death among 20 cases treated with sulphanilamide. During the first 10 months of 1939 the results of treatment of lobar pneumonia were as follows: serum treated cases 9, no deaths; sulphanilamide treated cases 4, one death; pyridine sulphanilamide treated cases 49, three deaths; serum or serum in conjunction with other therapy 20, no deaths. The latter group for the most part was a selected one in that it comprised early cases and received serum early in the disease. Cases treated with sulphanilamide alone or in combination with other therapeutic measures numbered 24 with one death. This group comprised selected cases in that the drug was given only when there seemed to be clear cut indication. In the pyridine sulphanilamide group it was necessary to formulate our own dosage. All of the three fatal cases were extremely ill and received the drug as a last resort.

In those cases where streptococci are present in the sputum we have found pyridine preferable to plain sulphanilamide. In the staphyloccus infections there seems to be little evidence that either of these drugs is of great benefit.

Dosage

With serum 100,000 units are given, followed later by more serum if the individual case seems to demand it, though many will have a crisis after the first 100,000 units.

Our doses of pyridine have been smaller than those recommended by others but our results compare favorably and our sequellae have been less frequent and less severe. We give 2 grains at once, then 1 grain every 4 hours day and night until temperature has been normal for 24 hours, then ½ grain every 4 hours for 6 doses. Children receive correspondingly smaller doses. Only three cases required hypodermoclyses because of vomiting. For this method 2 grains of the drug are dissolved in 1000 c.c. of 5% glucose or 1500 c.c. of normal saline at optimal temperatures. It may also be given intravenously in the same solution.

Blood Concentration

This is a great variable since cases on the same dosage for the same time have very different concentrations. We felt that the optimum is an individual matter and probably should be judged as much by the clinical picture as by the blood figures. Somewhere between 5 and 10 mg.% seems to be the average figure at which the drug is clinically active. In those cases who respond quickly and who have only small amounts there is rarely much danger. It is in the occassional case where therapy is long continued that concentration figures are invaluable. Here we run into the danger of secondary fever and other sequellae. It is the tendency to regard fever after an interim of afebrile days as a result of the disease process; but we must not forget that the drug may itself cause fever. In these cases the drug should be continued or begun again only after blood concentration has been studied. Both the free and total sulphapyridine in the blood should be known in these cases, as acetylation may take place unpredictably and procedure with the drug might be attended with grave risk or even fatal results.

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* Abstract of paper read before Greenwich Medical Society, Greenwich, Conn., Dec. 19, 1939.

Choice of Therapy

Serum when used should be given early in the disease, within the first three days from the onset. The case must be one for which a type specific serum is available at once. Rabbit serum seems preferable to horse serum. Pyridine sulphanilamide is the choice if the disease is advanced or if the sputum contains a pneumococcus for which a specific serum is not available. It may be used wisely if there is delay in typing the sputum or if the patient cannot afford serum. Some writers recommend combined serum and pyridine therapy, either early in group III pneumonias who appear very ill or in all patients coming in to the hospital late in the disease and appearing very ill.

Pyridine sulphanilamide should never replace serum as the latter under proper conditions will terminate the disease promptly and permanently. Pyridine apparently holds the disease in check until the normal body defences can step in and terminate the disease. Serum is not attended with the sequellae reported from pyridine and sulphanilamide, the worst effect being a violent serum reaction which is of short duration and rarely dangerous.

Advantages and Disadvantages of Pyridine Sulphanilamide

Pyridine is always available, easily administered and inexpensive. Its disadvantages are headache, dizziness, cyanosis (less marked than with sulphanilamide), nausea and vomiting in some instances. Fever definitely ascribed to the drug was noted in but two instances. Hemolytic anemia was noted in but two instances where it assumed any clinical significance and these yielded promptly to discontinuance of the drug. Icterus is usually present. During periods of active therapy a daily red blood count is advisable. Leukopenia was observed but once and may be forestalled by daily white blood counts. Gross hematuria was observed but once and that patient had microscopic blood in the urine on entrance to the hospital. Microscopic hematuria was observed in but five cases, no more than the rule in untreated cases.

Treatment with pyridine should be stopped if any of the following appear: abdominal pain, hematuria, icterus, anemia, leukopenia, fever, dermatitis, or hepatitis.

Home treatment with pyridine sulphanilamide must be guarded against as unsafe. Failure to hospitalize patients will result in failure to use serum and this in turn may result in less improvement of serum.

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1990 CSMS ANNUAL MEETING HIGHLIGHTS

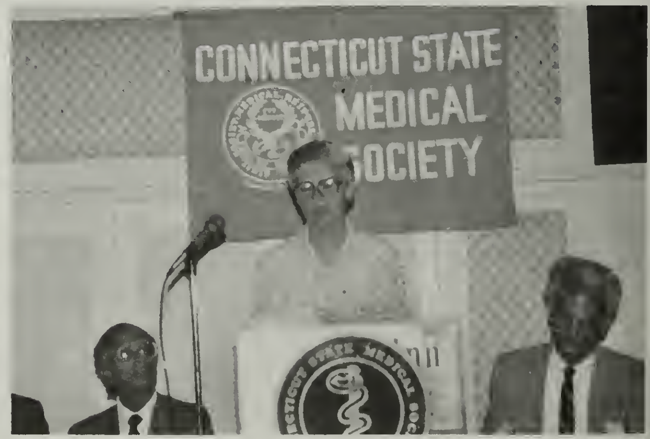
Frederick G. Adams, D.D.S., M.P.H., Commissioner, Connecticut State Department of Health Services addresses the House of Delegates with respect to the priorities of health services in Connecticut.

Newly inaugurated CSMS President, Mehdi S. Eslami, M.D., center, finishes his speech as Speaker of the House of Delegates, Kenneth M. Robbins, M.D., Middletown, right, and Vice-Speaker, Sultan Ahamed, M.D., Norwich applaud.

From left to right, President-elect, Anthony P. Redmond, M.D., President, Mehdi S. Eslami, M.D., Immediate Past President, Roger S. Beck, M.D., and Vice-President, Sultan Ahamed, M.D. listen to comments from the House of Delegates.

At a reception in his honor, Mehdi S. Eslami, M.D., 153rd President of CSMS, is congratulated by his daughter, Michelle Eslami, M.D.

Outgoing CSMS President Roger S. Beck, M.D., presents donations of AMM-ERF to James D. Kenney, M.D., left, of Yale University School of Medicine, and Carl F. Hinz, Jr., M.D., right, of the University of Connecticut School of Medicine.



Mrs. Joan Reed, President of the CSMS Auxiliary, gives her report to the House of Delegates.

From the Executive Director's Office

COUNCIL MINUTES

Thursday, June 14, 1990

Organizational Meeting

The organizational meeting of the Council for 1990-1991 was called to order by the President, Mehdi S. Eslami, M.D. Dr. Eslami expressed his appreciation and thanks to the Council for honoring him with the Presidency and to the New Haven County Medical Association for nominating him to that post. He stated that he has been a member of the Council in various posts for over 15 years. Following his remarks and introduction of all Council members, elections of a Chairman and a Vice-Chairman of the Council for 1990-1991 were held. It was VOTED to elect Joseph C. Czarsty, M.D., Oakville, Chairman, and Joseph S. Sadowski, M.D., Hartford, Vice-Chairman.

Attendance

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Ahamed, Blum, Bobruff, Brooks, Cottle, Deren, Eslami, Fox, Freedman, Hollister, Jr., Intravia, Kamens, Lesnik, McDonnell, Meridy, Orphanos, Parikh, Petrie, Petro, Redmond, Robbins, Sadowski, Sosa, Wetstone, Wolfson, Zanker, and Zeppieri.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Garofalo, Mrs. Connelly, Mr. Tomat (FCMA), Mr. Coffey (HCMA), Ms. Harney (NHCMA), and Mrs. David Reed, (President, Auxiliary).

Absent were: Drs. Beck, Chmieleski, Dardick, Franklin, Keating, Jr., Reyelt, Jr., Van Nostrand, and Welch.

Report of the President

Dr. Eslami reported that Anthony Redmond, M.D. attended the Massachusetts Medical Society Meeting for him and that he had attended the New London County Medical Association Meeting for Roger Beck, M.D. He discussed the upcoming 200th anniversary of the Connecticut State Medical Society, which coincides with the 200th anniversary of the Hartford County Medical Association. It was noted that Carl Heinz, M.D., is the Chairman of the Bicentennial Committee for Hartford and it was VOTED to appoint Craig Czarsty, M.D., Oakville, Chairman of the CSMS Bicentennial Committee and that the Chairman of the Council would appoint the other members of the committee. A councilor from Fairfield County informed Dr. Eslami that they would also be celebrating their 200th anniversary.

Dr. Eslami further reported that he had received a request from Hartford County to replace Robert Green, M.D., on the CSMS Committee on Insurance with Robert M. Pierro, M.D., Hartford, who is the current chairman of the HCMA Committee on Insurance. It was VOTED to approve this change.

He was requested to appoint Benjamin Gordon, M.D., Westport, on the Advisory Committee on AIDS of the Department of Health Services replacing Elihu York, M.D., Hartford, who resigned from the committee.

He also received a request from Robert Stein, M.D., Cheshire, asking that he be permitted to serve an additional year as Chairman of the CSMS Joint Practice Committee. It was reported that Victor Fortin, M.D., Hartford, was unable to accept the chairmanship this year. It was VOTED to approve the appointment of Robert Stein, M.D. as chairman for one additional year and also to note that this action was an exception to the policy of the three year tenure for chairmen and was not to be taken as a precedent.

Report of the Executive Director

Mr. Norbeck discussed a letter received from the State Department of Health Services inviting CSMS to participate in a coalition for a five-year program to reduce smoking in the State of Connecticut. The Department of Health Services and the American Cancer Society intend to submit an application to be one of 20 demonstration sites in this ASSIST (American Stop Smoking Intervention Study) project. Membership on the coalition would require a commitment of CSMS staff time beginning in July 1991 and there may be some subcommittee involvement. The Department of Health Services and the American Cancer Society would like a letter of intent from CSMS, if we decide to participate. CSMS will not be involved in any grant money whatsoever and will have no fiduciary responsibility. He reported that he could serve in the staff capacity, with help from Robert Brunell, if necessary. It is quite possible that as the program gets underway, they may ask for some physician involvement. Following a brief discussion, it was VOTED to participate in the coalition.

He further discussed items in the AMA Handbook for the forthcoming meeting which he felt would be of interest, having to do with the editorial policy of *JAMA* and *AM News*; a resolution being introduced by New York "directing that at least one page of *AM News* be allocated to the Chairman of the Board of Trustees to include any material felt to be appropriate, particularly material that has been turned down by *AM News* editorial staff; and a resolution being introduced by the Illinois delegation which states "That the House of Delegates establish a special committee of the Board or expand the authority of *JAMA* editorial board to review all proposed editorials and to determine and decide appropriateness of editorials developed by the Editor with the right to rejection to assure editorial comment is compatible with views and opinions of the publisher, which is the AMA".

Report of Auxiliary

Mrs. Joan Reed reported that the Auxiliary will now concentrate on building up county organizations instead of working on statewide projects. They have obtained names of potential leaders in the counties and plan to meet with them to plan strategy for the forthcoming year.

Report on M.D. Health Plan

Through the telephone speaker, Guy W. Van Syckle, M.D., Medical Director of M.D. Health Plan, gave the following update to the Council regarding M.D. Health Plan.

The Annual Shareholders meetings is scheduled for June 27th, beginning at 2:00 P.M. All members of the Council are urged to attend. He reported that 77% of the withhold will be returned shortly. At present 36,614 members have joined M.D. Health Plan and 2,460 physicians are now participating providers. April and May exceeded the hospitalization budget, however, the hospital days and admits per 1,000 continued to run under projections. The high costs in April and May were the result of an unusual group of very severe illnesses including several premature infants.

The Open Ended Product was implemented on June 1st and 300 members enrolled. It was anticipated that 85-90% of the members of this Product will use CSMS/IPA physicians. The TPA (3rd party administrator plan) will begin September 1st. This is specifically intended for employees who choose to self fund their own medical programs. M.D. Health Plan will provide quality assurance and utilization review. It replaces the Med Choice Plan which was offered jointly with Stirling and Stirling. The *Patterns* program of ambulatory review was begun on April 1st and through May 31st a total of 40,000 claims were reviewed. Of these, 138 fell outside the criteria. Following clinical review of these claims 8% were deemed inappropriate and physicians were subsequently notified and claims reduced or denied with the opportunity to appeal the decision. Because of perceived misunderstandings and misinterpretations of the program on the part of some of the physicians, and in keeping with the resolve to respond to the physicians concerns, the *Patterns* program was returned to the test mode. The evaluations will continue and physicians notified of utilization patterns which exceed the criteria, however, no financial reduction will be made to charges for a 90 day period. During this 90 day period, an active educational program will be carried out, including a presentation by the *Patterns* originator, Doctor Harrington, and informational seminars set up around the state stressing the need for appropriate and accurate coding. Also, the full implementation pointed out several problems with our present fee methodology which has not allowed proper updating of fee changes nor kept up with the CPT changes which have occurred since the original submission of fees in1986. A new fee methodology will be created to respond to these realities. Although the outlook for M.D. Health Plan continues to be bright, it will always require cooperation on the part of the physicians together with some constraints in utilization.

Appointments

It was VOTED to make the following changes in committees, representatives, etc.

Delegate to Maine Medical Association: Appoint Frank K. Abbot, M.D., Delegate, to replace Annemarie S. Welch, M.D. and appoint Anthony Redmond, M.D., Alternate Delegate.

Committee on Cooperation with Medical Schools of Connecticut: Appoint Brendan Fox, M.D., Chairman, replacing Herbert D. Lewis, M.D., who does not wish to be chairman but will remain on the committee.

CSMS Charitable Trust: Appoint Juan Sosa, M.D., as a trustee replacing Vincent Catrini, M.D.

Committee on Publc Affairs: Appoint Vittorio Ferrero, M.D., to replace A. William Bertuch, M.D., who is unable to serve.

M.D. Health Plan/MDEC: Nominate Stephen M. Upham, M.D., to replace Kenneth R. Dardick, M.D., who is unable to serve. This will fill the vacancy from Windham County.

Committee to Study Perinatal Morbidity and Mortality

Gerald J. Foye, M.D. Chairman of the subject committee, submitted a detailed report on the activities of the committee which included several recommendations concerning substance abuse involving the newborn, expanding the information on birth certificates, expansion of neonatal intensive care beds, etc. all of which require state funding. Following discussion, it was VOTED to accept the report with commendation and refer it to the Committee on Legislation for implementation of the recommendation concerning the expansion of neonatal intensive care beds.

Membership Development

Jerome Freedman, M.D., Chairman of the Ad Hoc Committee on Membership, reviewed the 1989 membership statistics outlining the loss of membership through resignations and/or non-payment of dues. The membership record for 1989 indicated a net increase in membership of 194, 65 more than in 1988. There were 457 new members elected in 1989, however there was a loss of 43 members due to deaths, 75 resignations, 10 transfers, and 135 for non-payment of dues. It was VOTED to approve Dr. Freedman's recommendation to restructure the Ad Hoc Committee on Membership as follows: the senior councilor from each county, AMA delegates, county and state executive directors, CSMS president and president-elect, student member representative, resident member representative, and the Auxiliary president. It was VOTED to instruct the committee to evaluate the problem, find possible solutions and report its conclusions to the Council and that Dr. Freedman continue as Chairman.

Life Members

It was VOTED to receive, as information, the names of the following physicians who have been granted Life Membership effective 1/1/90:

Robert L. Arnstein, M.D., Hamden (NH), Peter A. Arturi, M.D., Cos Cob (F), Edward R. Harvey, M.D., Seymour (NH), Joan A. Kadish, M.D., Norwich (NL), Manuel E. Kadish M.D., Norwich (NL), Margaret D. Kelly, M.D., Middletown (M), Joseph J. Kristan, M.D., Vernon (T), Henry Mass, M.D., Woodbridge (NH), Maria N. Nepomuceno, M.D., Mansfield Ctr. (W), Novello E. Ruggiero, M.D., Watertown (L), William F. Ryan, M.D., West Hartford (H), Melvin J. Sandler, M.D., Willimantic (W), Herbert E. Weisberg, M.D., Waterbury (NH).

Dates for Semi-Annual and Annual Meetings

It was VOTED to approve the following dates:

Semi-Annual Meeting of the House of Delegates, Wednesday, November 28, 1990

Annual Meeting of the House of Delegates, Wednesday, May 8, 1991

Scientific program, Thursday, May 9, 1991.

Council of New England State Medical Societies

Stewart Petrie, M.D. gave a brief report on the recent meeting of the Council of New England State Medical Societies. He reported that the various states reported and that Dr. McAfee addressed the group. He also asked for guidance on a resolution that was being introduced at the AMA House of Delegates concerning "Perinatal and Infant Mortality Reviews". It was VOTED to support the resolution.

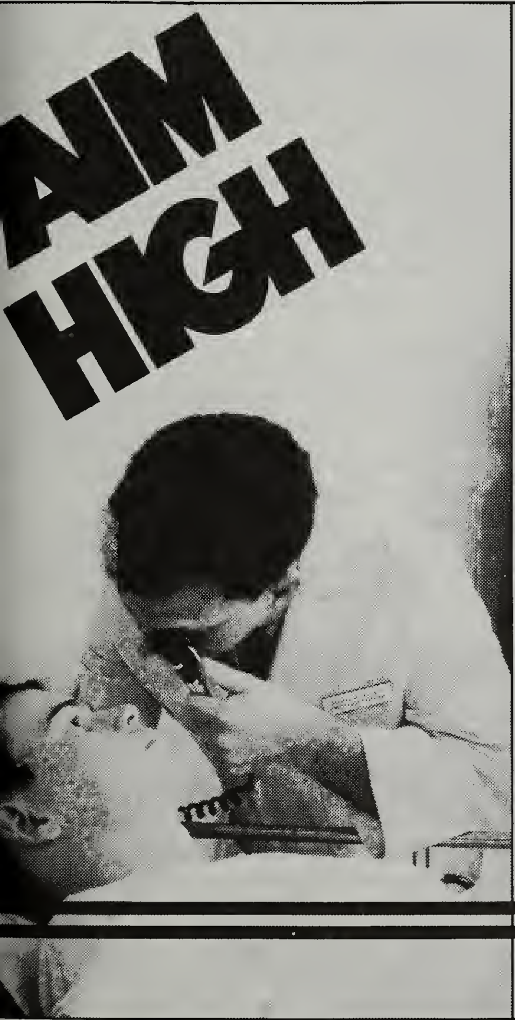
Dates for Future Council Meetings

Wednesday, July 25, 1990

Thursday, September 6, 1990

Wednesday, October 17,1990

N.B. The foregoing is a summary of the proceedings and actions of the Council on June 14, 1990. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for the perusal by any interested members of the Society.



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Oct. '90. Age 34. Presently in practice. Nat'l bds. AB cert. M.D., Medical College of VA; Int. and Res., Abington Hospital, Abinton, PA. Prefers group, associate or institutional type practice. Write, Jeffrey C. Ettinger, M.D., 501 Bryce Canyon Court, Petaluma, CA 94954.

Sept. '90. Age 33. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, Harvard Medical School, Boston; Res., University Hospitals, Cleveland. Prefers primary care, urgent care, adolescent or university health care type practice. Write, Barry Knishkowy, M.D., Sasqua Pond Rd., E. Norwalk, CT 06855.

INTERNAL MEDICINE

Aug. '90. Age 57. Licensed in Connecticut. Nat'l bds. AB cert. M.D., Boston University School of Medicine, Boston, MA; Int. and Res., Hartford Hospital, Hartford, CT. Prefers institutional or industrial type practice. JD Degree, New England College School of Law. Write, Charles A. Gundersen, M.D., 301 Tall Timbers Rd., Glastonbury, CT 06033.

Nephrology. July '90. Age 35. Licensed in Connecticut. FLEX. AB elig. M.D., Institute of Medicine & Pharmacy, Bucharest, Romania; Int. and Res., St. Barnabas Medical Center, Livingston, NJ; Fellowship, University of Medicine & Dentistry, New Jersey Medical School, Newark, NJ (Nephrology and Renal Pathology). Prefers group, assoc., institutional or solo practice. Write, Guy D. Sbar, M.D., 125 Elm St., Third Floor, Westfield, NJ 07090.

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Heart-Lung Transplantation: Initial Experience in New England

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ABSTRACT—Between May 1988 and June 1989, five combined heart-lung transplants were performed. There were two males, age 16 and 19 years, and three females age 33, 34, and 19 years. Three patients had primary pulmonary hypertension, one had cystic fibrosis, and the fifth had doxorubicin-induced cardiomyopathy with associated pulmonary hypertension. All patients were severely restricted in functional capacity and were oxygen-dependent. Four grafts were distantly procured (ischemic times 1:15, 2:35, 2:45, 3:45); one was procured on-site (ischemic time 0:58). Four of five grafts functioned well (Po_2 on Fio_2 30% postoperatively: 102, 120, 180, and 129 torr). One graft (distantly procured with an ischemic time of 1:15) showed total failure of oxygenation secondary to fluid overload during donor surgery; the recipient could not be weaned from cardiopulmonary bypass. All patients were extubated 24 to 30 hours postoperatively. Rejection episodes have been infrequent and all have been successfully treated with pulse steroids.

Four of the five patients are alive and well with normal cardiopulmonary function and normal functional capacity 15, 12, 8, and 6 months after surgery. Heart-lung transplantation is an effective therapy for properly selected patients with end-stage cardiopulmonary disease resulting from a variety of primary disorders.

Introduction

THE first successful heart-lung transplant was performed at Stanford, California, 1981.[1] This pioneering attempt was followed by the initiation of heart-lung transplantation at a handful of centers worldwide. With increasing experience and the advent of cyclosporine actuarial survival rate at one year now approaches 60-75%.[2] The most common recipient diagnoses have been primary pulmonary hypertension, congenital heart disease with Eisenmenger's syndrome, and cystic fibrosis.[3] Building on this clinical experience and on experience gained in the laboratory, a program of heart-lung transplantation was begun at Yale-New Haven Hospital in May 1988. This report summarizes the experience from May 1988 to June 1989.

Clinical Experience

Meticulous recipient evaluation and strict criteria for acceptance as a potential heart-lung recipient have been crucial in obtaining excellent clinical results. At Yale-New Haven Hospital potential recipients must be under the age of 45, New York Heart Association Class III or Class IV with an expected survival of less than one year, free of systemic infection (although pulmonary colonization is acceptable), stable from a psychological and social point of view, and have no history of major thoracic surgery. Relative contraindications include systemic disease (eg, severe peripheral vascular, systemic lupus erythromatous, or amyloidosis), moderate to severe prerenal azotemia or hepatic abnormalities, a history of central nervous system disorder, marked obesity, a history of alcohol or drug abuse, and a history of mental illness.

Using these criteria, 71 patients were referred for evaluation at Yale between May 1988 and June 1989. Ten of these patients died before evaluation could be completed. Twenty-four patients were not acceptable recipients. Thirty-seven patients were suitable candidates and were placed on the waiting list for organs through the United Network for Organ Sharing. Nine patients died while on the waiting list. Twenty-three patients are still awaiting organs. Five patients survived to receive heart-lung transplants.

The five patients for whom suitable heart-lung blocks were obtained included three females with primary pulmonary hypertension (ages 19, 33, and 34), one male with cystic fibrosis (age 19), and one male with doxorubicin-induced cardiomyopathy associated with pulmonary hypertension (age 16). The mean waiting

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Table 1
Criteria Which Suitable Heart-Lung Donors Must Meet

Donor Criteria:
Age Below 45 Years
$Po_2 > 100$ torr on 40% inspired oxygen
Normal lung compliance with peak inspiratory pressure below 20 mm Hg, tidal volume less than 15 mL/kg, and respiratory rate of 10-14 breaths per minute
No abnormalites on chest films
No major thoracic trauma
No past history of pulmonary disease
No systemic or pulmonary infection
Normal EKG
Suitable Cardiac Donor

time for a suitable organ was 81 days and ranged from one to 321 days.

Donor blocks for heart-lung transplantation were accepted only if several strict criteria were met. (See Table 1.) All donors were less than 45 years old, had Po_2 of greater than 100 torr on 40% inspired oxygen, and had normal lung compliance with peak inspiratory pressure below 20 mmHg, tidal volume less than 15 mL/kg, and respiratory rate of 10 to 14 breaths per minute. No radiographic abnormalities were present. No donor had suffered major thoracic trauma. None had active systemic or pulmonary infection or a past history of significant pulmonary disease. All electrocardiograms were normal. All donor hearts fulfilled criteria for cardiac transplantation.

All five grafts were obtained in a similar fashion. Four of the five grafts were procured at distant hospitals throughout New England. Ischemic times were one hour and 15 minutes, two hours and 35 minutes, two hours and 45 minutes, and three hours and 45 minutes. One graft was procured at Yale-New Haven Hospital. Its ischemic time was 58 minutes.

Distant procurement of heart-lung grafts is now being performed reliably at a number of centers. Nevertheless, the optimal method of preservation and perfusion of the donor organs is a matter of debate.[4] At Yale-New Haven, prostaglandin E_1 is used as a pulmonary vasodilator for 15 minutes prior to aortic cross clamping. Standard cold potassium cardioplegia is administered via the aortic root and a modified Euro-Collins solution (12 mEq of magnesium sulfate and 65 mL of 50% dextrose added per liter) is used as a pulmonary perfusate via the pulmonary artery (see Figure 1). The fraction of inspired oxygen is kept as low as possible (and always below 40%) throughout the period of donor evaluation and during operative removal of organs. Central venous pressure is kept as low as possible and every attempt is made to limit the amount of fluid administered to the donor. Methylprednisolone (30 mg/kg) is given intravenously at the start of the donor operation.

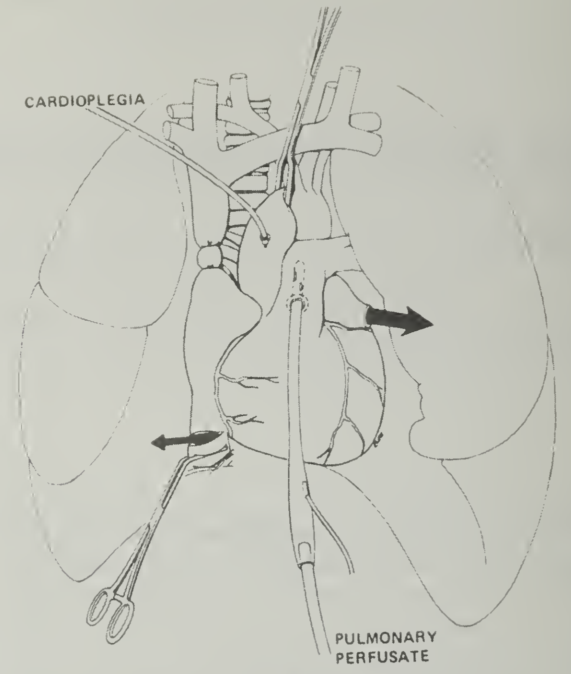

Figure 1
Diagram of catheter placement just prior to excision of heart and lungs from donor. (Reprinted from Baldwin, et al: *Ann Thorac Surg* 1987;43:670-3.)

The procedure is performed through a median sternotomy. The anterior pericardium and both phrenic nerves are removed prior to dissection and the ascending aorta, innominate artery, and both venae cavae are controlled. The azygous vein is divided. The trachea is encircled as high as possible and heparin (300 U/kg) given intravenously. Prostaglandin E_1 is administered via central venous catheter for 15 minutes prior to placement of the aortic cross clamp. An initial dosage of 10 ng/kg/min is increased to 80 ng/kg/min if mean systemic blood pressure is maintained at 55 mm Hg or greater. The aorta is cross clamped and cold (4° C) crystalloid potassium cardioplegia is given through the aortic root. The inferior vena cavae and left atrial appendage

Table 2
Preoperative Characteristics of Recipients

	*PT#1 PPH**	*PT#2 Cardiac failure with high PVR†*	*PT#3 Cystic fibrosis*	*PT#4 PPH**	*PT#5 PPH**
FEV_1	2.3	1.7	0.89	2.5	2.1
FVC	3.1	2.0	1.5	3.2	2.9
Oxygen dependent?	YES	YES	YES (intubated)	YES	YES
Pulmonary artery pressures (Systolic/Diastolic)	150/50	69/44	—	93/45	127/55

* Primary pulmonary hypertension
† Pulmonary vascular resistance

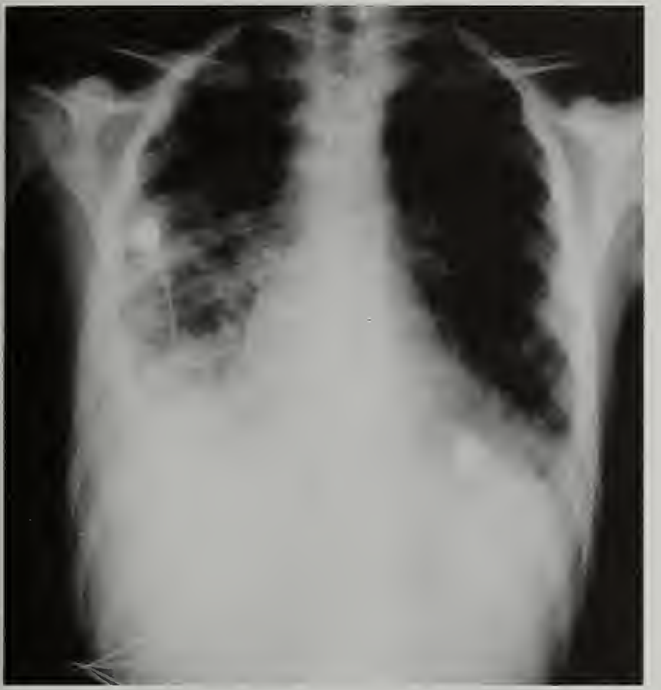

Figure 2a

a) Pulmonary rejection in patient 2 at 2 1/2 weeks postoperatively as documented by infiltrates on chest radiograph. b) Resolutions of rejection seven days after treatment with intravenous pulse steroids.

are promptly incised to prevent distension of either ventricle. Modified Euro-collins solution infuses through a catheter inserted in the pulmonary artery while continuous palpation guards against over distension. After perfusion of the heart and lungs, the trachea is stapled closed and the graft excised. It is transported in Physiosol solution at 4° C.

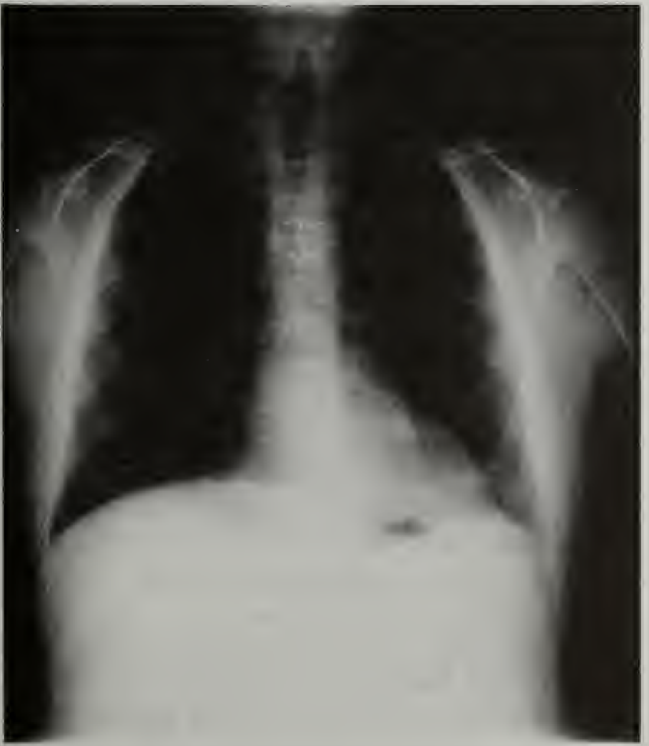

Figure 2b

Table 3
Episodes of Both Cardiac and Pulmonary Rejection Postoperatively. All Were Successfully Treated with Pulse Steroids.

PT #1:	No lung rejection Mild cardiac rejection at two weeks
PT #2:	Moderate lung rejection at 2 1/2 weeks Mild cardiac rejection at six weeks
PT #4:	Mild lung rejection at three weeks No cardiac rejection
PT #5:	Mild lung rejection at six weeks No cardiac rejection

Characteristics of the five recipients are shown in Table 2. The mean FEV$_1$ was 1.9 L, the mean FVC was 2.5 L. All five patients were oxygen dependent. One was intubated. Those patients with primary pulmonary hypertension had pulmonary artery pressures approaching systemic levels.

All recipient operations were performed through a median sternotomy. The pleura anterior to the pericardium was incised bilaterally to expose both lungs. All bleeding from pleural adhesions was controlled prior to heparinization. The pericardium was opened, taking care to preserve both phrenic nerves on pedicles. Aortic cannulation was carried out as high as possible. Two venous cannulas were placed and cardiopulmonary bypass initiated. The heart was removed with incisions at the level of the aortic valve commisures, the main pulmonary artery, and the left atrium at the atrioventricular junction. The left pericardium was excised 3 cm anterior to the left phrenic nerve. An incision was made posterior to the left phrenic nerve immediately anterior to the pulmonary veins. This incision was carried inferiorly to the diaphragm and to the pulmonary artery superiorly. The left pulmonary veins were freed from the posterior mediastinum taking care to preserve the left vagus nerve. The left pulmonary ligament was divided and the left lung retracted out of the wound. Bronchial collateral vessels were individually secured. The bronchus was exposed and stapled closed with 3.5 mm staples after transection of the pulmonary artery. The left lung was removed from the surgical field. An incision was then made 3 cm anterior to the right phrenic nerve and pericardium anterior to this incision removed. A second incision was made posterior to the right phrenic nerve. Again, a 3 cm pericardial pedicle including the right phrenic nerve was fashioned. The right pulmonary ligament was divided and the lung withdrawn from the chest. After the posterior pleura was divided, the right bronchus and pulmonary artery were divided. The right lung was removed from the surgical field. Bronchial artery collaterals were again secured. The trachea was exposed to the right of the aorta with traction applied to the left and right bronchi. Taking care to preserve the surrounding blood supply, the trachea was divided immediately above the carina and the distal segments removed. The donor heart

Figure 3a

Figure 3b

a) and b): Photographs of the first two heart-lung recipients in New England one year postoperatively.

and lungs were passed onto the field. Donor trachea was divided immediately above the carina. After cultures were taken of the donor trachea, the right lung was transferred to the right chest, passing beneath the right atrium and right phrenic nerve pedicle. The left lung was similarly passed beneath the left phrenic nerve pedicle. The tracheal anastomosis was performed with 3.0 polypropylene suture. Protection of the heart during implantation was maintained with continuous lavage of cold electrolyte solution via a catheter in the left atrial appendage. After completion of the tracheal anastomosis gentle ventilation began. An incision in the donor right atrium was made in a curvilinear fashion so as to avoid the sinus node. Anastomosis of donor to native right atrium was completed with continuous polypropylene suture. The aortic anastomosis was performed last with a continuous suture of polypropylene. The chest cavity was then emptied of fluid and the caval snares removed. Cardiopulmonary bypass was discontinued.

Results

Four of the five grafts functioned well. All these four recipients were extubated 24 to 30 hours postoperatively. Partial pressures of oxygen immediately after extubation on 30% oxygen by face mask were 102 torr, 120 torr, 180 torr, and 129 torr. One graft had total failure of oxygenation due to excess fluid administration during donor surgery. This was a distantly procured graft with a relatively short ischemic time of one hour and 15 minutes. The recipient could not be weaned from cardiopulmonary bypass.

The four survivors have had minimal problems with rejection as detailed in Table 3. The first recipient had no lung rejection and mild cardiac rejection at two weeks. The second had moderate lung rejection at two and one half weeks and mild cardiac rejection at six weeks. The fourth and fifth recipients had no cardiac rejection and only mild lung rejection at three and six weeks, respectively. Our fifth patient also had mild lung rejection at six weeks. All episodes of rejection were successfully treated with pulse steroids. Cardiac rejection was diagnosed using endomyocardial biopsy. Because of the well-described paucity of cardiac rejection in heart-lung recipients, we performed routine biopsies only at one and three weeks postoperatively.[5] Further biopsies were performed as indicated by the clinical course. Lung rejection was diagnosed using clinical criteria of fever, infiltrates on chest films, and absence of pathogenic organisms on thorough bacterial and viral cultures (including bronchoscopic examination and transtracheal aspiration). Resolution of cardiac rejection was documented by follow-up biopsy four to five days after completion of steroid pulses. Resolution of pulmonary rejection was documented by radiologic and clinical findings.

The chest roentgenogram of patient 2 showing moderate lung rejection is shown in Figure 2a. He had a low

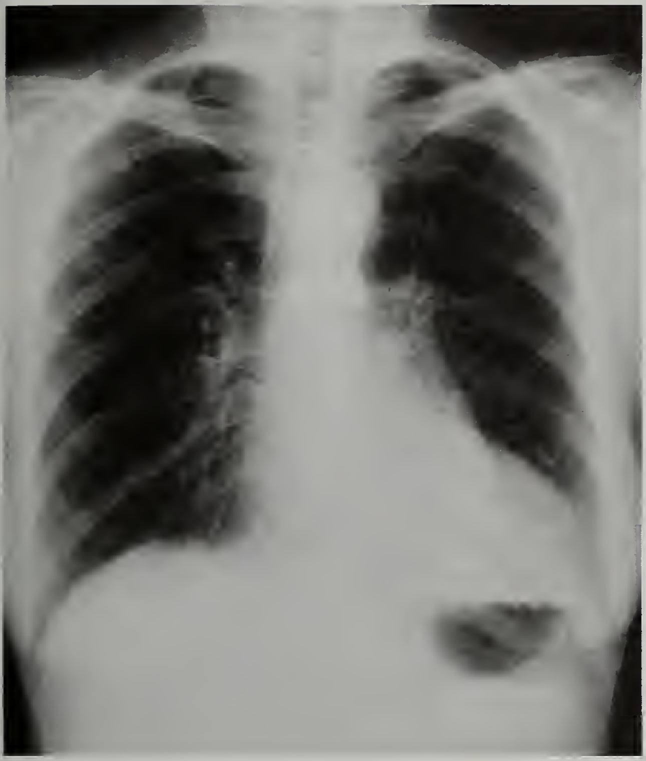

Figure 4a

a)-d): Chest radiographs of heart-lung recipients postoperatively. Figures a and b are at one year postoperatively of patients 1 and 2. Figures c and d are at six months postoperatively of patients 4 and 5.

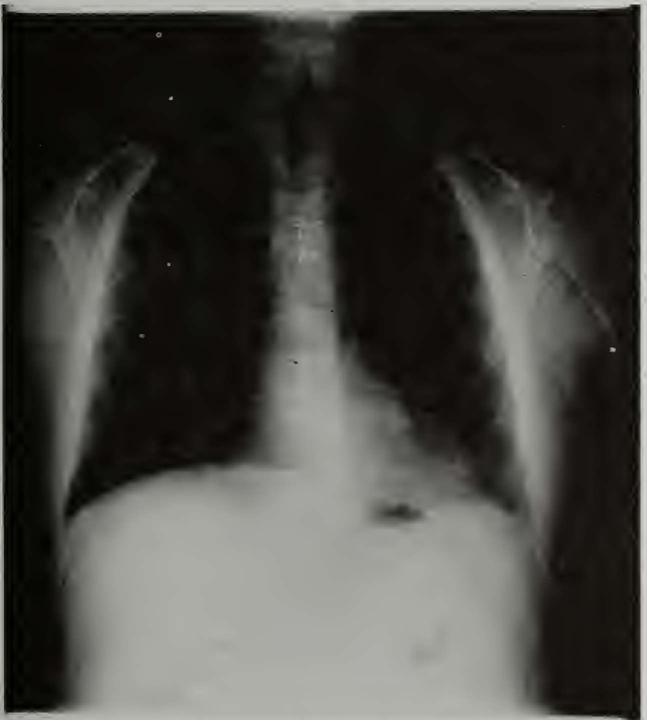

Figure 4b

grade fever and no growth in multiple bacterial and viral cultures from multiple sites including a transtracheal aspirate. The clear chest x-ray one week after treatment with 1g of intravenous methyl-prednisolone each day for three days is shown in Figure 2b.

Infections have been infrequent. One recipient had a urinary tract infection which was successfully treated with antibiotics for 14 days. No other infections have occurred.

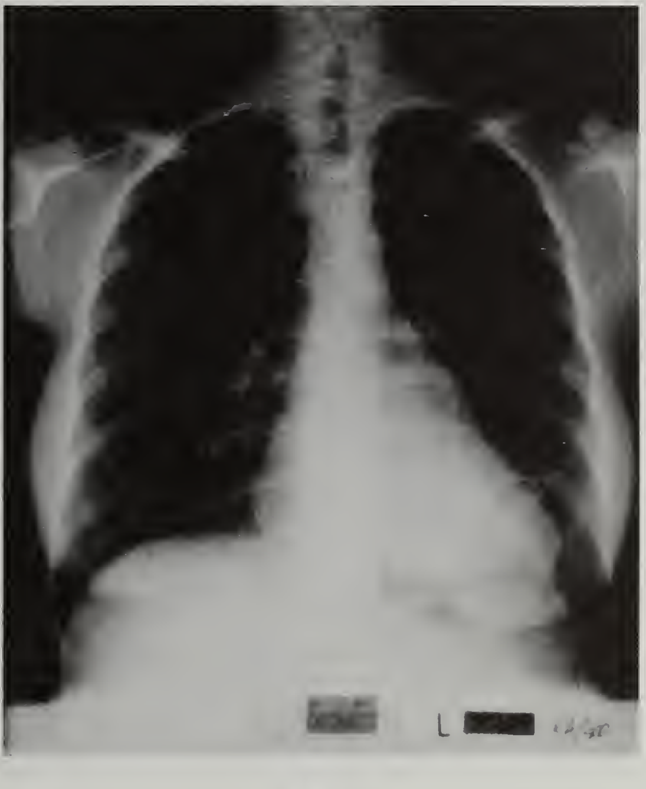

Figure 4c

Bronchiolitis obliterans, felt to be a form of chronic rejection, has been noted by chest radiography in other heart-lung recipients as early as six months postoperatively.[6] Although our longest survivor is now 15 months from transplant, we have not yet noted any such findings.

Currently four of five patients (80%), are alive and well with normal cardiopulmonary function 15, 12, eight, and six months after surgery. Photos of our first two patients are shown in Figure 3. Representative AP chest radiographs of all four recipients are shown in figure 4.

Discussion

Combined transplantation of the heart and lungs can be carried out efficiently and effectively. Reported one year survival is currently 60% to 75%.[2] The actuarial survival rate at Yale-New Haven is currently 80% at one year as the result of rapidly improving techniques in the field.

Distant procurement of donor organs using a prostaglandin E_1 infusion prior to harvesting of the donor organs has been a key factor in the continued improvement. Prostaglandin E_1 is a pulmonary vasodilator which when given prior to aortic cross-clamping in a dose of 20 ng/kg/min to 80 ng/kg/min allows more uniform perfusion and rapid cooling of the pulmonary vasculature and parenchyma. Other groups have used a similar regimen successfully.[7]

The main limitations in heart-lung transplantation are pulmonary preservation and the shortage of appropriate donor organs. Nearly twice as many patients in our series

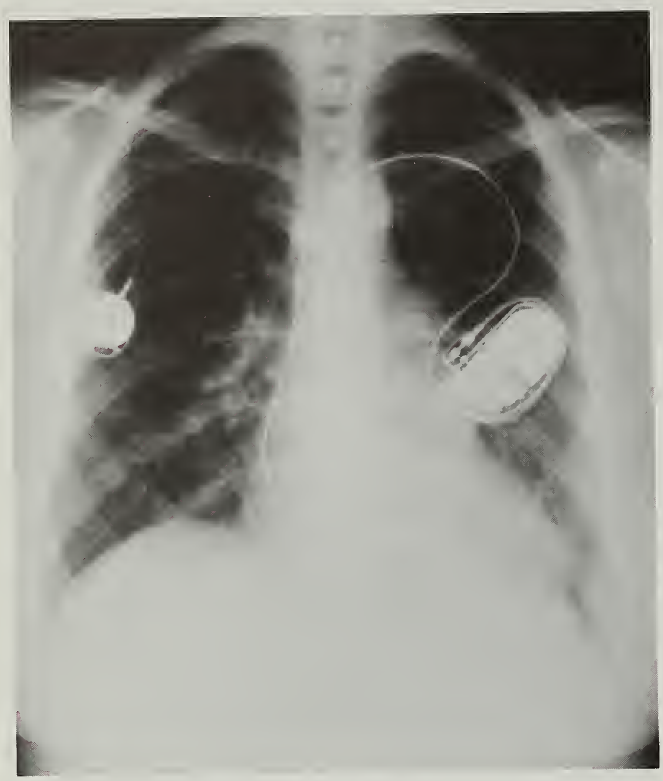

Figure 4d

died awaiting suitable organs as survived to transplantation. It has been estimated that fewer than 10% of all appropriate cardiac donors will be appropriate heart and lung donors. Public education about transplantation is mandatory to ameliorate the donor shortage, and further experimental work on pulmonary preservation is necessary.

Conclusion

Heart-lung transplantation is an effective therapy for properly selected patients with end-stage cardiopulmonary disease resulting from a variety of disorders.

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Babesiosis in a Connecticut Resident

WILLIAM ALWARD, M.D., MANSUR JAVAID, M.D., AND JOSEPH GARNER, M.D.

ABSTRACT—Fewer than 200 confirmed cases of babesiosis have been reported in the last decade. Most cases in the United States have occurred on Cape Cod, Nantucket Island, and Long Island. *Babesia microti*, a malaria-like protozoan that parasitizes erythrocytes, is responsible for this illness in the United States. Infection is often subclinical but may be fulminant, especially in infants, the elderly, and in asplenic patients. Symptoms are nonspecific, usually consisting of fever and myalgias. Common laboratory abnormalities include evidence of hemolysis and thrombocytopenia. We report a case of babesiosis in an elderly male manifested by high fevers, confusion, hemolytic anemia, and thrombocytopenia.

BABESIOSIS is an uncommon disease that was first described in animals by Babes in 1888 and first clearly recognized in man by Skarbalo and Deanovic in 1957.[1,2] The initial report of this disease in the northeastern United States appeared in 1970.[3] Babesiosis remains a rare disease as there have been fewer than 200 confirmed cases reported in the United States during the last decade.[4] Most cases have been reported from well-known endemic areas of the northeastern United States, such as Nantucket Island, Martha's Vineyard, and eastern Long Island. Although most infected individuals are asymptomatic or experience only mild symptoms, the elderly constitute one group at greater risk for clinically significant illness.[4,5] We report a case of babesiosis in an elderly male which was accompanied by significant thrombocytopenia and hemolytic anemia.

Case Report

A 78-year-old man with moderately severe Alzheimer's disease presented with weakness, anorexia, and increase in his usual level of confusion for two days. He had a history of carcinoma of the bladder that had been treated with transurethral resection, diverticulitis, a sigmoid polyp treated with a left hemicolectomy, and arteriosclerotic heart disease with congestive heart failure. He had not had a splenectomy.

In the emergency room he was disoriented. His oral temperature was 39.1° C, pulse 70, blood pressure 118/70 mm Hg, and respirations 18 per minute. His neck was supple. His lungs were clear to auscultation, and percussion. There was a grade III/VI systolic ejection murmur at the cardiac apex. Examination of the abdomen was unremarkable. Neurologic examination was normal except for confusion. Admission laboratory data showed a white-cell count of 8,100 with 61% polys, 5% band forms, 1% eosinophils, 1% basophils, 13% lymphocytes, 3% atypical lymphocytes, and 16% monocytes. Hemoglobin and hematocrit were 12.1 gm/dl and 36% respectively. Platelet count was 62,000. Electrolytes were normal; total bilirubin was 1.4 mg/dl and the serum aspartate aminotransaminase (AST) was 62 IU/L. The chest film revealed cardiomegaly and aneurysmal dilation of the ascending aorta unchanged from previous radiographs. A computed tomographic scan of the head showed moderate cerebral atrophy. A lumbar puncture was normal. A blood smear done on the day following admission showed intra- and extraerythrocytic forms diagnostic of *Babesia* species (see Figs. 1 and 2). Four percent of his erythrocytes were parasitized at that time. The patient lived in central Connecticut, but had attended an outdoor party in a wooded area near Montauk, Long Island, four weeks prior to the onset of his illness. There was no recollection of a tick bite. The patient had not visited any other areas known to be endemic for babesiosis during the preceding year and had not received a blood transfusion. There had been no opportunity for exposure to malaria.

His fever rose to 39.7° C during the next two days. It was decided to initiate anti-babesial therapy because of his age, high fevers, increasing confusion, and progressive thombocytopenia. Therapy was begun with clindamycin 600 mg intravenously every eight hours and qui-

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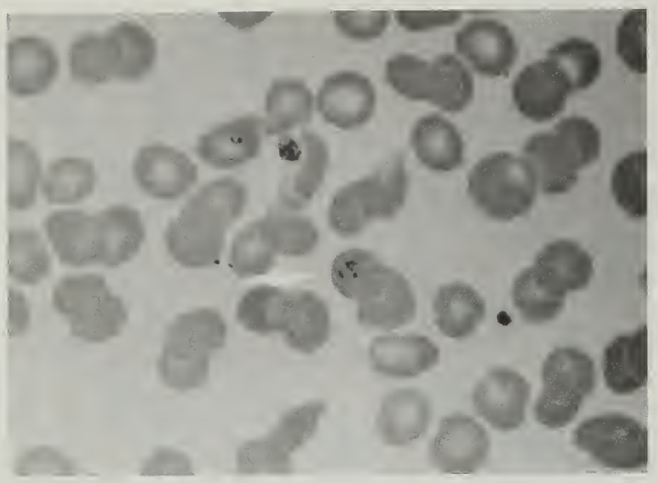

Figure 1
Intracellular parasitic forms characteristics of *Babesia* species.

nine 650 mg orally daily beginning on the third hospital day. On the fourth hospital day the platelet count decreased to 40,000. His hemoglobin and hematocrit declined to 8.6 gm/dl and 25% respectively, accompanied by a rise in lactate dehydrogenase to 695 IU/L and hemoglobinuria. His haptoglobin level fell to less than 10 mg/dl. Blood, urine, and cerebrospinal fluid cultures were negative. A Lyme titer was negative. His fever and confusion improved following initiation of treatment and he became afebrile on the sixth day of therapy. His platelet count steadily increased, reaching 386,000 by the ninth hospital day. Following transfusion of two units packed red blood cells his hematocrit increased to 30% and remained stable. The percentage of parasitized cells progressively decreased after initiation of clindamycin and quinine until parasitemia resolved completely by the sixth day of treatment. He received eight days of clindamycin and quinine therapy. At the time of a follow-up visit two weeks later he had no symptoms of babesiosis and examination of his blood smear showed no parsitized erythrocytes. Symptoms had not recurred one year later.

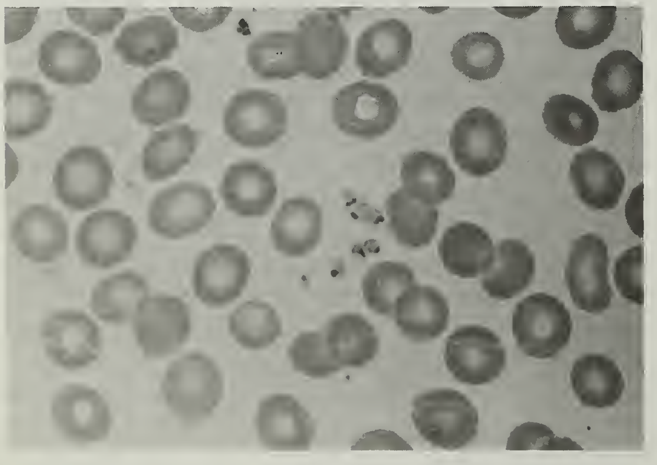

Figure 2
Extracellular parasitic forms of *Babesia* species.

Discussion

Human babesiosis in the United States is caused by the intraerythrocytic protozoan parasite *Babesia microti.*[6] Its primary reservoir is the white-footed deer mouse and its vector is *Ixodes dammini,* the same tick responsible for transmission of *Borrelia burgdorferi*, the causative agent of Lyme disease. Although our patient acquired his infection in eastern Long Island, Connecticut physicians should be aware that a focus of babesiosis has recently been reported in the area of Old Mystic and Mystic, Connecticut.[4] This apparent extension of the endemic zone of babesiosis is not surprising given the ever-widening distribution of *I. dammini,* and it seems likely that babesiosis will begin to appear in additional areas where Lyme disease is endemic. Groups at increased risk for developing severe symptomatic illness include the elderly and functionally asplenic individuals.[4,7] As longevity increases and there are more active elderly, it is highly likely that clinically significant babesiosis will be seen more often in this age group. It is also important to note that since babesiosis is transmitted by the same vector as Lyme disease, simultaneous infection may occur. A study by Benach et al[8] examining patients from Long Island found that 54% of patients with babesiosis had positive Lyme serology, and simultaneous infection with *B. microti* and *B. burgdorferi* has been reported.[9]

The majority of cases of babesiosis are either subclinical or are mild, self-limited illnesses characterized primarily by fever, myalgias, and malaise.[10] Common laboratory findings include thrombocytopenia and hemolytic anemia, just as were seen in our patient.[4,6] Initial diagnosis usually depends on microscopical examination of Giemsa-stained blood smears since clinical signs and symptoms are nonspecific. In babesiosis, in contrast to malaria, schizonts and gametocytes are not present, extracellular forms are seen, there are no intraerythrocytic pigment granules, and as many as 12 parasites per erythrocyte may be present.[11] A travel and exposure history coupled with careful examination of blood smears can thus differentiate babesiosis from malaria. The diagnosis can also be substantiated with either serological techniques or animal innoculation.[12]

Since most infections with *B. microti* are subclinical or mild, it follows that specific therapy is not always indicated. The relatively small number of treated cases has made determination of optimal therapy difficult and a variety of regimens, including pentamidine with chloroquine, diminazene aceturate, and exchange transfusion have been used.[13] Animal studies and anecdotal clinical reports have led most authorities to recommend treatment with clindamycin and quinine in patients who experience severe illness due to babesiosis.[14] Our patient began to improve only after initiation of this regimen. Prevention of babesiosis involves avoiding tick bites in endemic areas. Taking prudent steps such as wearing long pants tucked snugly into boots and applying tick repellent to clothes can be highly effective in preventing infections transmitted by *I. dammini.*

Babesiosis is a disease that Connecticut physicians will undoubtedly be seeing more often in the future. Although symptoms are nonspecific, clinically consistent illness in a patient with an opportunity for exposure should lead to a careful review of blood smears looking for characteristic intraerythrocytic parasites. The clinical course is usually benign, but patients with severe illness based on clinical or laboratory findings may benefit from specific therapy of their *B. microti* infection. Finally, patients who have babesiosis should be evaluated for evidence of infection with *Borrelia burgdorferi.*

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M.D. Health Plan Coding Seminars Set for CSMS-IPA Members and Staffs

MD Health Plan/CSMS-IPA is sponsoring a one day seminar designed for participating physicians and their office staff. The program entitled “Coding Essentials, ICD-9CM/CPT/HCPCS” is scheduled for the following locations and dates statewide for easy accessibility:

East Hartford, CT October 15th
Ramada Inn
100 East River Drive

Bridgeport, CT October 17th
Days Hotel (Ottavio’s)
815 Lafayette Blvd

Meriden, CT October 16th
Days Inn
900 East Main Street

Norwich, CT October 18th
Sheraton Plaza
One Sheraton Plaza

Bristol, CT October 19th
Quality Inn
42 Century Drive

8:00 - 9:00 Registration
9:00 - 4:30 Program
12:00 - 1:00 Luncheon

Codes drive the reimbursement system...a skillful coder is increasingly recognized as a valuable asset in every medical practice.

This seminar will guide your efforts to code a patient’s conditions accurately and completely, proving the “medical necessity” of the physician services...reducing denials and the frequency with which the payers downcode your services.

Mark your calendars! Use registration information mailed to you in August or contact MD Health Plan, ext. 700 for more information. Space is limited! Registration deadline: *October 12, 1990.*

Access to Care for Children and Adolescents with Disabilities

ROBERT A. KRAMER, M.D.

ABSTRACT—A survey of Connecticut pediatricians indicated that 90% of the respondents intended to provide care to children with disabilities. However, only 72% provided wheelchair access and only 68% accepted Medicaid reimbursement. Details of barrier-free design are presented and systems of support for the special needs of disabled patients are described.

THE Newington Children's Hospital has been addressing the secondary and tertiary needs of children and adolescents with disabilities for over 90 years. Technology and science have substantially altered the hospital's repertoire in meeting the needs of these young people, and thus, their potential for habilitation and participation in the mainstream of society. What used to be exclusively hospital-based care now has become possible on an ambulatory basis. Furthermore, what used to be considered exclusively the province of a specialty children's hospital has become possible, to a meaningful degree, in the private office setting. This is of particular importance in the area of primary health care. However, for the primary health care private office and clinic to become truly accessible to the child with disabilities, both physical and economic barriers must be overcome.

In the course of both specialty and routine care of many of these young patients it is reported that barriers to care in the community are a source of continuing frustration. Families often request guidance in finding physician or clinic facilities that are barrier free. They are concerned about the child's ability to enter a physician's office or the examining room, as well as the ability to pay for this care.

In order to estimate the prevalence of these barriers a survey was mailed to 694 Connecticut pediatricians in an attempt to identify those whose practices were open to the primary care of children and adolescents with disabilities. The questionnaire further asked if the office facilities were wheelchair accessible, and finally, whether the practice accepted Medicaid reimbursement. The results of the survey were as follows: 195 (28%) practices responded to the questionnaire. No data are available to allow comparison of the responding practices to the nonresponders.

Of the 195 responses the following data were obtained:

Private practices providing services to children with disabilities	176 (90%)
Practices that are wheelchair accessible	140 (72%)
Practices that accept Medicaid	133 (68%)

These data show that, although 90% of Connecticut pediatricians responding to the survey perceived that their practices were open to children with disabilities, only 72% had offices that were wheelchair accessible and only 68% accepted Medicaid. These responses indicate a significant difference between perception and reality.

The requirements for barrier-free access to an office may be beyond the experience or training of most physicians. Table 1 lists the highlights of the basic components for accessibility and usability for physically disabled individuals in the design of buildings and facilities. These data come from the American National Standards Institute Report to the President's Committee on Employment of the Handicapped. The questionnaire only asked if the office was wheelchair accessible. To determine accurately if the office is barrier free each of the items in Table 1 would have to be evaluated.

In order to interpret the significance of a physician's nonacceptance of Medicaid reimbursement it is necessary to examine the national data on the underinsured. In this respect children are among the most seriously affected citizens of our society. A few facts about health care access:[2]

1) Approximately 16 million children and adolescents through age 21 have no health insurance coverage whatsoever. Many more have inadequate insurance, particularly in respect to services for the disabled.

2) The number of uninsured children increasd by 14% between 1981 and 1986. This is attributed to the increase in the number of children living in poverty and the diminution of private, employer-based insurance for dependents.

3) The uninsured child population does not fit the poverty stereotype. Rather, the majority of uninsured

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ROBERT A. KRAMER, M.D., Executive Vice President, Newington Children's Hospital Foundation, Inc., Newington; Clinical Professor of Pediatrics, Orthopedics, and Rehabilitation, Yale University School of Medicine.

Table 1[1]

Design Considerations for Barrier-Free Access

1. Accessible parking, passenger loading zones, sidewalks, and building entrances.
2. Corridors, hallways, passageways, and aisles all constructed to allow the maneuvering of wheelchairs and/or individuals on crutches, as well as appropriate ramps, elevators, or platform lifts.
3. Windows and doors that can be operated by a wheelchair-bound or otherwise disabled individual.
4. Drinking fountains and water coolers that are appropriately sized and placed for wheelchair access.
5. Bathrooms and toilets that are appropriately sized and placed for wheelchair access, mobility, and transfer. Soap and towel dispensers that are placed to be accessible.
6. Storage facilities including cabinets, shelves, etc that are appropriately sized and placed.
7. Safety equipment such as grip bars.
8. Signs to indicate routes and/or resources that are particularly appropriate for disabled patients.
9. Public telephones that are sited to be accessible.
10. Waiting room space, play areas, table access that are accessible to wheelchairs and/or otherwise disabled patients.
11. Examining or treatment rooms and examining tables that allow wheelchair mobility and easy transfer.

hildren live in two-parent, white families where there is t least one full-time employed parent earning an income bove the poverty line.

4) Eighty-seven percent of uninsured children in 1986 ived in families with at least one working parent.

5) The studies reveal that the lack of insurance reduced tilization of medical services. For example, 65% of nsured disabled children visit a physician at least once a ear, while only 42% of uninsured disabled children nake one physician visit per year. This discrepancy is ven more dramatic when one examines minority popuations, such as Hispanic children.

6) The health insurance coverage of children with isabilities has been documented for ages 10 - 18 in the ational Health Interview Survey. Adolescents with disbilities are twice as likely to be on public funds as those ithout disability.[3]

The significance of these data is further compounded y the fact that the actual reimbursement rates in Con-ecticut from Medicaid for a child's initial office visit has een $23.40 since 1985 with follow-up visits reimbursed t the rate of $18.70.[4,5]

The problem of underinsurance for the children of our ociety has become the top priority of the American cademy of Pediatrics for the next few years. The cademy proposes that health insurance be provided for ll children up to age 21, and that each state be required to stablish a fund for the purchase of private health insu-ance for all children currently qualifying for Medicaid, as ell as those whose families are uninsured or underin-ured and not eligible for Medicaid.[2]

The financial disincentives to seeking health care, whether it be for the disabled child, the child with acute illness, or the child requiring preventative health care are among the most serious barriers to the access of care.

In addition to access to medical care, most children and families coping with major disabilities need access to a diversity of support services.

In established centers for the care of disabled patients the use of multidisciplinary teams is the standard for case management. No single professional has enough knowledge or experience to address all of the requirements for habilitation of the patient. Each profession brings its own knowledge and experience to the task. Typically one professional is assigned the responsibility for assimilating all the input from each team member, and coordinating all of the data into a plan for the patient.

In the practice setting much of the effectiveness of the team approach can be replicated through access to the public and private agencies in the state which provide information, advocacy, and direct services to the disabled. In Table 2 is a list of such resources.

Table 2

Support Services for Chronically Ill or Disabled Children and Their Families

Association for Children with Learning Disabilities (ACLD) (236-3953) or CALD (838-5010)

Board of Education and Services for the Blind (1-800-842-4510 or 249-8525).

Capital Region Education Center (688-7333)—For birth to three and early intervention programs.

Commission for the Deaf and Hearing Impaired (566-4826)—Help with school issues and interpreter services.

Connecticut Association for Retarded Citizens (CARC) (233-3629)—Provides information and referrals.

Connecticut Birth to Three Interagency Service Coordination Center (953-8151)—Assists in identifying and coordinating screening, assessment, and program services to infants and toddlers with developmental concerns.

Connecticut Legal Services (347-7237; 235-2571)—Legal assistance.

Connecticut Parent Advocacy Center (739-3089 or 1-800-414-CPAC)

Connecticut Self Help Mutual Support Network (1-800-842-1501)—Information on support groups.

Connecticut State Department of Education
  Complaint Office (1-800-842-2200)
  Special Education Services (638-4273)
  Birth to Three Programs and Pre-School (638-4273)

Department of Children and Youth Services (566-3536)—Care Line (1-800-842-2288, ext. 40; 24 hours).

Department of Income Maintenance (566-2008)—Title XIX (medical insurance). Eligibility is based on stringent income standards but access is sometimes available for middle-class families through the Katie Beckett Waiver.

Department of Mental Retardation (528-7141)—Respite, early intervention, case management, placement issues, and sometimes resources for services and equipment.

Division of Rehabilitation Services (1-800-874-7687)—Information on local Easter Seals Rehabilitation Centers. Also Camp Hemlocks for Disabled Children.

Table 2 (Cont.)
Support Services for Chronically Ill or Disabled Children and Their Families

Families Make a Difference (574-4084)—Matches families and older adult volunteers. Serves Hartford, Bloomfield, Manchester, East Hartford, and West Hartford.

Hartford Association for Retarded Citizens (HARC) (525-1213)—Provides weekend programming and summer camp.

InfoLine Capitol Area (522-INFO)—Provides free information on health, welfare, and mental health education, recreation, government agencies, and much more.

Newington Children's Hospital Social Services Department (667-5350)—Provides short-term counseling, information, and referral, crisis intervention, and advocacy for patients and their families.

Office of Protection and Advocacy for Handicapped and Developmentally Disabled Persons (297-4300; 1-800-842-7303; TDD-566-2102)—Information, referral, and case advocacy.

Parents Anonymous (523-5255)—For parents finding it especially hard to cope with all the stresses.

Sibling Information Network (282-7050)—Developed a support group for brothers and sisters of children and disabilities.

Social Security Office - Local (566-2247)—Information of Supplemental Security Income SSDA/Disabled Children's Program for low income families.

Special Education Resource Center (1-800-842-8678 or 632-1485)—Assistance for professionals and provision of appropriate education for children and youths with special needs.

Time Out for Parents (728-6914 - Hartford, 649-5700 - Manchester)—Provides child care, time for yourself, support in parenting, community information.

United Cerebral Palsy (236-6201)—United Cerebral Palsy Association in difference regions of the state offer diverse programming to people with a variety of disabilities, not only cerebral palsy.

The results of this survey suggest that, among the responding pediatricians practicing in Connecticut, there is the intent to provide services for children with disabilities, but that both physical and fiscal changes in their practice organization will be necessary to fulfill this promise.

In respect to physical access, there are substantial data in the architectural literature as well as in the federal guidelines to achieve appropriate standards. In respect to fiscal access it is apparent that a substantial number of children with disabilities get all of their health insurance from Medicaid. A significant number of children are either underinsured or uninsured. The medical community should become advocates for reform of health insurance coverage for children. This effort may be coordinated with the nation campaign of the American Academy of Pediatrics.

Although the management of each patient with a pediatric disorder traditionally has been the responsibility of the individual physician, whether in practice or clinic setting, the requirements for the habilitation of the disabled patient presents a special challenge to the practitioner. For those committed to this challenge there are substantial resources in the community equally committed to the task and ready for a productive partnership in behalf of the patient.

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Acknowledgements:

The material in Table 2 was compiled by Gretie Charlot-Wright, CISW, and Carolyn Longo, MSW, of Newington Children's Hospital Departmentof Social Services.

Special thanks go to Ms. Susan Romanow whose efforts in collating the responses and organizing the material were invaluable.

Abstracts of Papers

SCIENCE SYMPOSIUM DAY AT BRIDGEPORT HOSPITAL

FOREWARD: The Annual Bridgeport Hospital Science Symposium Day was held on 29 March 1990. A total of 28 abstracts were submitted and 26 papers were presented. In all, the papers were coauthored by 56 individuals. Of these, 15 were residents or fellows, 31 attending physicians, and 10 nurses, physician assistants, and other allied health personnel. From papers given by the residents, the best one was selected by a faculty committee and the author received a certificate and a $100 award at graduation.

Mitchell Schorow, Ph.D., Director of Medical Education, Bridgeport Hospital.

Detection of Liver Metastasis on an Ultrasound Image Utilizing Microcomputer Analysis

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A study was conducted to determine if a microcomputer based system, equipped with a frame-grabber and utilizing statistical analysis, can distinguish between sonographically normal livers and those containing metastatic lesions.

A sample of 74 consecutive patients (mean age 60 years; range 16-91 years) underwent sonographic examinations of the liver using an Acuson-128 system with a 3 Mhz phased array transducer. All patients' diagnoses were known beforehand. A single sonographer obtained images from 56 normal and 18 abnormal livers (metastatic disease). Two standard views of normal livers were obtained. These included a sagittal view of the right lobe without vascular structures and a transverse view of the right lobe at the bifurcation of the right portal vein. Abnormal liver images contained areas of metastatic deposits without vascular structures. Gain and depth controls were individually adjusted for optimum picture clarity. Utilizing an IBM PC/AT compatible computer system, 168 regions of interest were obtained from the 74 patients. Linear discriminant analysis was applied with 21 quantitative features including 13 first order and six second order statistics, as well as two image gradients.

The results showed that when sagittal views of normal livers were compared with abnormals, the computer gave correct classifications for 88% of the images; sagittal normal and transverse normals were 79% correct; and, transverse normal and abnormals, 64% correct. These results indicate that a microcomputer can be used to access directly an ultrasound video display for identification of liver metastisis.

Axillary Dissection Should not Be Omitted on the Basis of Small Tumor Size or Nonpalpability of Invasive Breast Cancer

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JOHN D. MACARTHUR, M.D., and MARVIN A. MCMILLEN, M.D.,
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Axillary dissection is a routine part of the radical and modified radical mastectomies which until recently has been the standard of care for resectable breast cancer. Increased patient awareness, breast cancer screening, and mammography have resulted in many patients with nonpalpable or small lesions presenting themselves for treatment. Breast preserving operations have become common as the number of patients with small tumors has increased. Axillary dissection is often omitted in cases of nonpalpable breast cancer. Patients with the smallest tumors are most likely to have axillary dissection omitted. Ommission of axillary disection in these patients may be justified if nodal involvement is unlikely or if the prognosis is not affected by the findings. To determine whether it is reasonable to omit axillary dissection on the basis of nonpalpability or size alone, we set out to determine the following: the incidence of axillary nodal involvement in the smallest detectable tumors (those measuring 1 mm or less); the incidence of nodal involvement for nonpalpable tumors; and, the survival and recurrence rates for patients with axillary involvement with a nonpalpable primary.

Over the nine-year period from 1979 to 1988, 128 biopsies for nonpalpable breast cancer were performed. Of the 128, 44 (34%) were in situ and 84/128 were invasive. Of the 44 patients with in situ lesions, 19 had axillary dissections performed. All of these axillary dissections were negative. Of the 84 patients with invasive lesions, 69 had axillary dissections performed.

Fourteen of the 69 (20%) had positive axillary nodes. Of these 14, three were aneuploid and 10 were diploid by FACS analysis (one specimen was insufficient). In those with nodal involvement, the five-year cancer specific survival was 64% and the five-year disease free survival 38%. The average time of recurrence was 32 months from diagnosis and the average time of death was 42 months. All of the patients who had recurrent disease or died had received a full course of drugs, cytoxin methotrexate 5-FU or cytoxin adriamycin 5-FU. In addition, all cases of breast cancer measuring 1 mm or less reported to the Connecticut Tumor Registry over the years 1983-86 were reviewed. There were 137 cases. Twenty-two (16%) of these patients had axillary nodal involvement.

The incidence of axillary nodal involvement in nonpalpable invasive breast cancer and in tumors measuring 1 mm or less is 20% and 16% respectively. The prognosis for patients with nonpalpable breast cancer is strongly associated with the presence of nodal involvement. In cases where a positive axillary dissection will not influence future therapy or where the lesion is insitu, axillary dissection may probably be safely omitted. In our opinion, however, omission of axillary dissection solely on the basis of small tumor or nonpalpability is not justified.

Hypertension in Puerto Ricans: A Community Health Center Experience

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The 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure[1] states that "little information is available to determine whether Hispanics among other ethnic groups respond differently than Whites to anti-hypertensive therapy." Although information on Black and Mexican Americans is slowly evolving, for Puerto Ricans (PR) it is nonexistent. PR comprise the second largest Hispanic group following Mexican Americans in the United States.

This is the first reported study to analyze the efficacy of various antihypertensive agents in PR. During a one-month period, April 1989, 69 hypertensive patients were seen at the Bridgeport Community Health Center. The prevalence of high blood pressure (HBP) during the study period was 21%. A questionnaire addressing patient comprehension of HBP, socioeconomic data, and a survey of barriers to medical care was administered to 48/69 (70%) of the patients.

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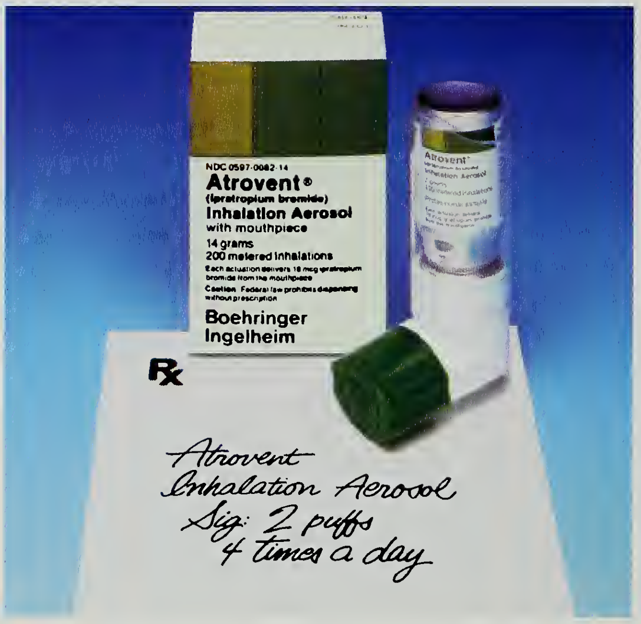
WARNINGS Atrovent® (ipratropium bromide) is not indicated for the initial treatment of acute episodes of bronchospasm where rapid response is required.

PRECAUTIONS General Atrovent® (ipratropium bromide) should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction.

Information for Patients Patients should be advised that temporary blurring of vision may result if the aerosol is sprayed into the eyes.

Patients should be reminded that Atrovent is not intended for occasional use, but rather, in order to be maximally effective, must be used consistently as prescribed throughout the course of therapy.



Drug Interactions Atrovent has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines, steroids and cromolyn sodium, commonly used in the treatment of chronic obstructive pulmonary disease, without adverse drug reactions. There are no formal studies fully evaluating the interactive effects of Atrovent and these drugs with respect to effectiveness.

Carcinogenesis, Mutagenesis, Impairment of Fertility Two-year oral carcinogenicity studies in rats and mice have revealed no carcinogenic potential at doses up to 1250 times the maximum recommended human daily dose for Atrovent. Results of various mutagenicity studies were negative.

Fertility of male or female rats at oral doses up to approximately 10,000 times the maximum recommended human daily dose was unaffected by Atrovent administration. At doses above 18,000 times the maximum recommended human daily dose, increased resorption and decreased conception rates were observed.

Pregnancy *TERATOGENIC EFFECTS Pregnancy Category B.* Oral reproduction studies performed in mice, rats and rabbits (at doses approximately 2,000, 200,000 and 26,000 times the maximum recommended human daily dose, respectively) and inhalation reproduction studies in rats and rabbits (at doses approximately 312 and 375 times the maximum recommended human daily dose, respectively) have demonstrated no evidence of teratogenic effects as a result of Atrovent. However, no adequate or well-controlled studies have been conducted in pregnant women. Because animal reproduction studies are not always predictive of human response, Atrovent should be used during pregnancy only if clearly needed.

Nursing Mothers It is not known whether Atrovent is excreted in human milk. Although lipid-insoluble quaternary bases pass into breast milk, it is unlikely that Atrovent would reach the infant to an important extent, especially when taken by aerosol. However, because many drugs are excreted in human milk, caution should be exercised when Atrovent is administered to a nursing woman.

Pediatric Use Safety and effectiveness in children below the age of 12 have not been established.

ADVERSE REACTIONS Adverse reaction information concerning Atrovent® (ipratropium bromide) is derived from 90-day controlled clinical trials (N = 254), other controlled clinical trials using recommended doses of Atrovent (N = 377) and an uncontrolled study (N = 1924). Additional information is derived from the foreign postmarketing experience and the published literature.

Adverse reactions occurring in greater than one percent of patients in the 90-day controlled clinical trials were as follows (ipratropium bromide N = 254; metaproterenol sulfate N = 249): *Cardiovascular:* palpitations — 1.8% *v* 1.6%. *Central Nervous System:* nervousness — 3.1% *v* 6.8%; dizziness — 2.4% *v* 2.8%; headache — 2.4% *v* 2.0%. *Dermatological:* rash — 1.2% *v* 0.4%. *Gastrointestinal:* nausea — 2.8% *v* 1.2%; gastrointestinal distress — 2.4% *v* 2.8%; vomiting — 0% *v* 1.2%. *Musculoskeletal:* tremor — 0% *v* 2.4%. *Ophthalmological:* blurred vision — 1.2% *v* 0.8%. *Oro-Otolaryngeal:* dry mouth — 2.4% *v* 0.8%; irritation from aerosol — 1.6% *v* 1.6%. *Respiratory:* cough — 5.9% *v* 1.2%; exacerbation of symptoms — 2.4% *v* 3.6%.

Additional adverse reactions reported in less than one percent of the patients considered possibly due to Atrovent® (ipratropium bromide) include urinary difficulty, fatigue, insomnia and hoarseness.

The large uncontrolled, open-label study included seriously ill patients. About 7% of patients treated discontinued the program because of adverse events.

Of the 2301 patients treated in the large uncontrolled study and in clinical trials other than the 90-day studies, the most common adverse reactions reported were: dryness of the oropharynx, about 5 in 100; cough, exacerbation of symptoms and irritation from aerosol, each about 3 in 100; headache, about 2 in 100; nausea, dizziness, blurred vision/difficulty in accommodation, and drying of secretions, each about 1 in 100. Less frequently reported adverse reactions that were possibly due to Atrovent include tachycardia, paresthesias, drowsiness, coordination difficulty, itching, hives, flushing, alopecia, constipation, tremor, mucosal ulcers.

Cases of precipitation or worsening of narrow-angle glaucoma, acute eye pain and hypotension have been reported.

A case of giant urticaria with positive rechallenge has been reported from the foreign marketing experience (see CONTRAINDICATIONS).

HOW SUPPLIED Atrovent® (ipratropium bromide) Inhalation Aerosol is supplied as a metered dose inhaler with mouthpiece. Each 14 gram vial provides sufficient medication for 200 inhalations. NDC 0597-0082-14. Each actuation delivers 18 mcg of ipratropium bromide from the mouthpiece.

Consult package insert before prescribing. AT-BPI-8/88

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Efficacy of blood pressure control was assessed by averaging the three most recent BP recordings (usually office visits within the previous three to six months). Good control was present in 88.4% (61) of the patients, fair control in 10.1% (7), and poor control in 1% (1). Forty-eight (70%) of the patients were on monotherapy. The treatment menu included: diuretic therapy, 36 (52%), with 20 of these patients (56%) receiving diuretics as monotherapy, beta-blockers, nine; ACE inhibitors, nine, and calcium channel agents, seven. Other confounding conditions were present in the study population which affect HBP control and therapy.

For the 48 patients who completed a questionnaire, their socioeconomic data revealed that 34 (71%) were receiving city welfare or state assistance, eight (16%) were uninsured, and six (13%) were privately insured. Although 12 patients (25%) were illiterate and 34 (71%) were non-English speaking, 22 (46.6%) knew the names of their medications and 41 (85%) knew the complications of hypertension. All patients reported cost as the most significant obstacle to receiving medical care, language barrier was noted by almost all (96%), and access to medical care was acknowledged as another barrier in 98% of the BCHC patients.

Compared to the reported experience of Black Americans, Puerto Rican patients in our sample seem to respond better to diuretics. Additionally, despite the PR poverty rate of 43% and the significant sociocultural differences, control of BP and patient education in a community health center is effective and improves the quality of life for these patients.

[1] The 1988 Report of the Joint National Committee on Detection Evaluation and Treatment of High Blood Pressure, U.S. Department of Health and Human Services, Public Health Service, 1988.

Efficacy of Combined Spatula/Cytobrush Smear for Cervical Sampling

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Improved rates of detection of cervical squamous carcinoma and dysplasia is contingent on adequate sampling of the transformation zone. The detection has been markedly enhanced with widespread use of the cervical cytobrush including a one-slide combined spatula/brush technique as published in the Netherlands (1986).

In an attempt to improve the detection rate of cervical intra-epithelial neoplasia and cope with the current shortage of cytotechnologists, we instituted the combined spatula/cytobrush technique in 1988. We then conducted a retrospective review comparing the results obtained with this method (1988,1989) with the traditional two-slide spatula/cotton swab smears used in 1987.

A total of 16,050 cases were examined in 1987, 11,957 in 1988, and 11,976 in 1989. 98% of smears were satisfactory. The cytobrush provided abundant well-preserved endocervical cells comparable to the cotton swab. Unsatisfactory smears increased slightly in 1988 and 1989 in clinic patients as a result, we believe, of the increase in the number of cyto-samples, and the more frequent encounters with heavy inflammatory exudates.

The overall detection of condylomas/squamous intraepithelial lesions of low grade increased (1987 - 1.7%; 1988 - 1.9%; 1989 - 2.6%). This was mainly appreciated in the clinic population (4.3% in 1987; 4.6% in 1988; 11% in 1989). Epidermoid carcinoma in situ showed a slight increase. The detection of adenocarcinoma did not improve.

Despite improved sampling techniques, 83 "interval dysplasias" were detected by screening previously negative smears in patients with cervical neoplasia detected by Pap smears or biopsies. The interval varied from one month to one year.

Reevaluation of the 83 smears showed 79 satisfactory samples reflecting sampling errors, 7.9% reclassified as unsatisfactory, and 3.6% as interpretative errors. In-service education facilitated widespread cytotechnologist and physician acceptance. Combined spatula/cytobrush is cost effective, reduces screening time, and improves detection of condyloma/squamous low-grade, intraepithelial lesions. More frequent screening may reduce potential sampling errors in high-risk patients.

Citations:

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Pancreatic Pseudocysts: Reassessment of Surgical Timing Based on Earlier Detection

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Modern imaging techniques have resulted in earlier detection of pancreatic pseudocysts during the course of pancreatitis. In this setting, previous recommendations regarding the timing of surgical drainage may require reassessment. In order to evaluate this possibility, a 10-year retrospective review of pseudocystic surgery (n=111) was undertaken in three general surgical units, including a Veterans Hospital (VA), a university-affiliated community hospital in the United States (CH), and a university hospital in the United Kingdom. There were 58 patients (52%) who underwent surgical drainage. Among these patients, 48% had urgent procedures for sepsis, hemorrhage, or gastrointestinal or biliary obstruction, while 52% underwent elective surgery. Patients undergoing urgent surgical drainage had a significantly increased risk of perioperative morbidity and mortality when compared to the elective group (p<.0001, chi-square). In order to evaluate the relative contribution of ongoing acute pancreatitis (AP) and the age of the pseudocystic on surgical outcome, the following analysis was performed:

Pseudocyst age:	<6 WEEKS		≥6 WEEKS	
Pancreatitis	AP	No AP	AP	No AP
Morbidity:	9/13	1/5	9/29	2/11
Mortality:	3/13	0/5	1/29	0/11

The presence of ongoing AP as determined by clinical criteria was strongly associated with perioperative complications both for mature and immature pseudocysts (p< . 0001, chi-square). While pseudocyst drainage less than six weeks following diagnosis was also predictive of poor outcome, this applied only to patients with ongoing AP.

In the absence of AP, the age of the pseudocysts had no effect on surgical outcome. The data suggest that, in patients requiring surgical drainage, complication rates are dependent on the presence of ongoing AP rather than the age of the pseudocyst. With current trends towards earlier pseudocyst detection, the presence of concomitant AP may be increasing. Surgical drainage in this setting should be avoided. In patients without AP, however, pseudocyst management may be optimized by draining at the time of presentation.

Diagnosis of Pancreatic Cystic Lesions: Cytologic Examination and CEA Assay of Cyst Content

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Differentiating pseudocysts from cystic neoplasms of the pancreas has therapeutic implications. Warshaw[1] has reported the limited specificity of cyst fluid amylase content in discriminating these lesions. Other studies, [2,3,4] including ours, have supported the use of carcinoembryonic antigen (CEA) content as an adjunct to cytologic examination in enhancing diagnostic accuracy. We have now expanded our study to include 41 cyst contents from 32 patients. Simple and/or complex cystic lesions were detected by computed tomographic scans and/or ultrasound in patients with a prior history of alcoholic pancreatitis, jaundice, and weight loss. Cysts varied from 2 cm to 15 cm, and involved mainly the head and body of the pancreas.

Of the 41 cysts that were examined, 33 were ultrasound-directed aspirates, six were found during surgical exploration, and two at the time of pathologic examination. Sediment was examined cytologically using the Papanicolaou stain and the supernatent was assayed for amylase and CEA (monoclonal, Abbott Laboratories). Diagnoses were correlated with biopsy or resection (five patients) and clinical follow up (after two years). Final diagnoses were; cyst/cystadenoma (13), pancreatic carcinoma (9), pseudocyst (16), islet cell carcinoma (1), microcystic adenoma (1), metastatic epidermoid carcinoma (1). The sensitivity of the cytological analysis for the diagnoses of carcinoma and mucinous cystic lesions was 62%, and the specificity was 100%. The mean amylase content in pseudocysts (47,176 U/L), mucinous cysts (13,396 U/L), and pancreatic carcinomas (419 U/L) were of limited discriminating value. The mean CEA content was found to be: pseudocysts (55.3 ng/ml), pancreatic carcinomas (344.3 ng/ml), mucinous cystic lesions (1572.4 ng/ml).

Using 5 ng/ml as the cutoff, CEA has a sensitivity of 100% and a specificity of 68%. By increasing CEA to 10 ng/ml cutoff, the specificity was increased to 80%. Elevated CEA values alone diagnosed three of nine pancreatic carcinomas and four of 13 mucinous cystic lesions. Adjunctive use of cyst fluid amylase and CEA with cytologic examination is encouraged preoperatively for appropriate patient management.

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Effectiveness of a New CK-MB Assay for Evaluating Acute Myocardial Infarction

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We studied the sequential changes of creatine kinase isonzyme MB (CK-MB), lactic dehydrogenase isoenzyme-1 (LD1), and the LD1/total LD ratio in 60 patients, 30 of them with a diagnosis of acute myocardial infarct, and the remainder unequivocally without infarction. We measured the values of the enzyme tests and the optimum time of sampling using Shannon information theory to find the best decision points that would discriminate between disease and nondisease with fewest errors. The decision cutoff values are derived from the difference in entropy between the base of the correlation of the tests and the base in which the correlation is minimized. Using this approach we find that a time of six hours after admission divides the patients into two major classes with the resulting ability to identify acute myocardial infarction based on decision values of: CK-MB >3.2 μg/L (ng/ml) using a monoclonal assay free of interference from CK-BB and macro-BB; LD1 >47 U/L; and LD1/total LD >27%. The new test appears to have value for monitoring the use of thrombolytic agents with particularly stringent time requirements for testing.

Carcinoembryonic Antigen (CEA) in Fine Needle Aspirates of Liver: A Diagnostic Adjunct to Cytology

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Carcinoembryonic antigen (CEA) was measured in 57 consecutive fine needle aspirates of liver to determine whether elevated levels could predict the presence of carcinoma in cytologically negative aspirates. There were 46 malignant and 11 benign lesions. Highest mean CEA values (298-880 ng/ml) were obtained in metastatic adenocarcinoma of the colon, stomach, and pancreas; lower levels (13.5 - 215 ng/ml) in metastatic carcinoma from breast and lung. Carcinoid, hepatoma, Hodgkin's Disease, and benign liver aspirates had low (<5 ng/ml) levels. Cytologic diagnosis of malignancy was 96% sensitive and 100% specific. Using 5 ng/ml as a cutoff for malignancy, the overall sensitivity of CEA for detection of malignancy was 65% and of adenocarcinoma alone, 85%; specificity was 100%. CEA content of the fine needle aspirates generally exceeded serum values by 10 to 100 fold. Though CEA content did not enhance sensitivity of cytologic diagnosis, it may suggest metastatic carcinoma of the gastrointestinal tract in patients presenting with adenocarcinoma from an unknown primary source.

Association of Mammographic Patterns with Biological Markers in Breast Cancer

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A study was conducted to determine if there were mammographic patterns associated with tumor characteristics that affect biological behavior.

A retrospective review of mammograms from 81 consecutive cases of biopsy proven breast carcinomas was performed. An experienced mammographer classified all 81 lesions by radiographic appearance into those that were spiculated (37); smoothly circumscribed (13); focal density (13); calcifications without a mass (10); and nonvisible (7). The presence of malignant calcifications was also classified (43). Pathological analysis included histological and nuclear grading using the Fisher method (n=57), estrogen receptor (ER) (n=65), and progesterone receptor (PR) assays (n=63), as well as DNA ploidy (n=67) using flow cytometry. Chi-square analysis was used for statistical evaluation.

Of the 65 cases that had an ER assay, 43% (28) had spiculated tumors and the remainder included all other types. Spiculated tumors were ER-rich (ER >20 fmol/mg) in 86% (24) of cases versus 46% (17) of nonspiculated lesions. The X2 (10.69) for spiculation and ER was statistically significant, P<.01, showing a significant positive predictive association. In the 63 cases with a PR assay, 48% (30) had spiculated tumors. Spiculated tumors were PR-rich (PR >20 fmol/mg) in 73% (22) of cases versus 51% (17) of nonspiculated lesions. However, this association did not achieve statistical significance. No radiographic association was found for DNA ploidy, nuclear grade, or histological grade.

These results indicate that spiculated tumors have a higher probability of being ER and PR rich.

Diagnosis of *Helicobacter pylori*-Associated Gastritis by Immunoblot Analysis

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The presence of *Helicobacter pylori* (formerly *Campylobacter pylori*) in gastric tissue has been associated with gastritis, duodenitis, and peptic ulcers. The diagnosis of helicobacter disease is generally made from the histological examination, culture, or demonstration of the presence of a rapid urease test from tissue obtained during endoscopy. A noninvasive test for *H. pylori* would be useful in diagnostic decisions and evaluating the efficacy of therapy. We investigated whether or not a definitively characterized antibody response to *H. pylori* could be a useful diagnostic tool.

A standard strain of *H. pylori* obtained from the American type culture collection was electrophoresed in polyacrylamide gels and then transferred to a solid support using standard methods for the production of Western immunoblot strips. The molecular weights observed were similar to those reported by other investigators. Using this method we studied the IgG and IgA response to *H. pylori* in 211 serum specimens obtained from 208 patients who had undergone endoscopy with biopsy. Each specimen was examined by Gram's stain, culture, and routine histological stains. Serum specimens had been obtained at the time of endoscopy and kept frozen at -20 C.

Preliminary results indicated that the IgG response to specific proteins of the microorganism may be used to distinguish *H. pylori* associated disease from other causes of gastritis. Further analysis may allow us to diagnosis the type or extent of the disease.

The Evolving Indications for Liver Biopsy in Managing Patients with Suspected Liver Disease

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After noticing a 75% decrease in the number of transjugular liver biopsies performed in high-risk patients with diffuse hepatic disease, we decided to investigate the clinical reasons for the decline.

All liver biopsies performed from 1979 through 1988 were retrospectively analyzed. Liver histologic specimens were obtained by nonguided percutaneous transperitoneal approach, the transjugular route, or the open surgical approach. Cytological material was obtained by thin needle aspiration under ultrasound or computed tomographic scan guidance. The number and success rate of each method of biopsy were tabulated on a yearly basis, as well as the clinical indications for each procedure. We assigned the clinical indications for each procedure to one of four broad subgroups: 1. patients with documented alcohol abuse and stable clinical condition; 2. patients with documented alcohol abuse and sudden deterioration in clinical condition; 3. patients without documented alcohol abuse but with presumed metastatic disease; and 4. patients with liver dysfunction but no history of alcohol abuse or presumed metastatic disease.

We found a general decrease in the number of liver biopsies over the 10-year period except for guided cytological aspirates. The general decrease has occurred for all clinical indications except for the exclusion of metastatic disease.

Contrary to long-standing teaching, histologic confirmation of diffuse hepatic disease does not appear to be as helpful in patient management as once had been believed.

Effectiveness of Measuring Concentrations of Prostate-Specific Antigen in Serum

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Prostate-specific antigen (PSA) is a glycoprotein demonstrated to have value as a marker in serum of patients with prostate carcinoma because its mean concentration in serum is proportional to the clinical stage of carcinoma and it is more sensitive than prostatic acid phosphatase (PAP) for monitoring remission. We examined the measurement in serum of PSA and PAP concentration in patients with benign prostatic hypertrophy (BPH), prostatitis, and adenocarcinoma of the prostate, to determine what PSA concentrations in serum are critical for medical decisions. The common occurrence of cases of BPH and prostatitis in the same population as those with prospective carcinoma with increased concentrations of PSA made it necessary to find the concentration of antigen in serum that would best segregate patients with high from intermediate or low risk of adenocarcinoma of the prostate, or distant metastases.

We used the measurement of entropy, a decision theory for information, to find critical values in the correlated database which we can then use to convert the data to a binary coded message that could segregate patients with minimum misclassification. The decision points, analagous to an upper limit in the disease-reference range, were at PAP = 0.75 U/L and PSA> 22.8 μg/L (ng/ml). PSA concentration in serum above 22.μg/L may be considered indicative of carcinoma of the prostate, stage C or D, until this diagnosis is proved unlikely. At PSA between 11.3 and 22.8 μg/L there is a 60%/40% split between benign disease and prostate carcinoma.

Helicobacter pylori: Identification by Touch Preparation

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The Warthin-Starry silver stain has been accepted as the gold standard for the demonstration of *Helicobacter pylori* (HP). Occasionally, where surface mucus and glands where HP reside, they may fail to stain despite repeated efforts. While "touch preps" of stomach tissue are accepted for gastric cytology and Papanicolaou stain for the detection of bacterial vaginosis, use in the detection of HP has not been reported. We investigated the adjunctive use of Papanicolaou stained gastric touch preps for detection of HP and compared the results to the Warthin-Starry stain on tissue sections of the same biopsy.

The advantages of the Papanicolaou technique would be: 1) ease of interpretation of bacteria in surface mucus and gastric cytology, 2) widespread availability in all laboratories (automated stain), 3) inexpensive reagents, 4) lack of necessity for special technical expertise, 5) rapid turn-around time. We studied 69 consecutive gastric antral biopsies from patients with endoscopic evidence of antral gastritis and/or peptic ulcer disease. A biopsy was obtained from within 3 cm of the pylorus, pressed on a glass slide for the touch prep and immediately placed in formalin for routine histologic examination and the Warthin-Starry stain. The touch prep was immediately spray-fixed and stained by the Papanicolaou stain. Results of the Papanicolaou stain were interpreted independently of the knowledge of the Warthin-Starry stain. Twenty-five patients had helicobacter (13 both techniques, two touch prep only, 10 biopsy only).

The sensitivity of the touch prep-71.4% biopsy was 92.5%. The combined sensitivity was 100%. Chronic active gastritis was present in 33 patients, 24 of whom had HP detected. False negative touch preps (10) resulted from unsatisfactory smears (2), and duodenal touch preps being used instead of antral biopsies (4). Adjunctive use of touch prep enhances detection of HP and provides ideal material for gastric cytology, and may serve as a cost-effective alternative to the expensive and difficult to perform Warthin-Starry silver stain.

Hypertension in Hispanics: Prevalence and Treatment

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Hypertension in the Hispanic community has yet to be completely addressed and evaluated. Not until the recent Hispanic Health and Nutrition Evaluation Study (HHNES), conducted by the United States Public Health Service, has the Hispanic population been independently assessed for health-related concerns on a large scale.

Our study was performed to assess the prevalence, control, and knowledge of hypertension in the community, and to conduct a comparative analysis with a hypertensive sample from the Bridgeport Community Health Center (BCHC).

One hundred eighty-one patients screened for hypertension drawn from various community locations, and 48 hypertensives at BCHC were given a questionnaire.

The prevalence rate for hypertension in the community sample was 45.3% (82 persons). Sixty-four (35.3%) participants indicated they had high blood pressure (HBP). Of the 117 community participants who stated they did not have HBP, 18 (15.4%) were actually found to have an average recording of greater than 140/90. Thirty-two (50%) of the community sample claimed their HPB was uncontrolled. The mean blood pressure (BP) for the 181 community sample was 161/63.

Forty-two (88%) of the BCHC patients were in good control with BP recordings less than 140/90. The average BP was 127/75.

Additional information of the knowledge base and socioeconomic information was obtained from both groups.

We found the extent of hypertension in the Hispanic community was significantly high (45.3%). The role of the health center in all aspects of patients care, viz., knowledge, treatment, and control of HBP, is critical in the management of Hispanic patients with hypertension.

Important Advances in Clinical Medicine

Preventive Medicine and Public Health

The Scientific Board of the California Medical Association presents the following inventory of items of progress in preventive medicine and public health. Each item, in the judgement of a panel of knowledgeable physicians, has recently become reasonably firmly established both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in preventive medicine and public health that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Preventive Medicine and Public Health of the California Medical Association, and the summaries were prepared under its direction.

Advances in Prenatal Screening

PRENATAL screening tests address two types of problems: maternal diseases that can affect the health of the fetus or newborn, and fetal anomalies or diseases that may not have effective treatments. Examples of screening tests for maternal diseases include maternal hemoglobin, rubella titer, Rh factor, tuberculin skin testing, and tests for sexually transmitted diseases. An example of testing for fetal defects is amniocentesis for women older than 35 years.

In recent years, several other maternal diseases that can affect the fetus have been recommended for screening. In 1988 the Centers for Disease Control recommended that all pregnant women receive hepatitis B screening regardless of their risk status. As many as 65% of mothers who test positive for the hepatitis B surface antigen have no known risk factors, and if the mother is positive there is a 90% chance of neonatal acquisition with the attendant morbidity and mortality. Prompt immunization of infants with exposure to hepatitis B can be protective. The Second International Workshop-Conference on Gestational Diabetes and the American Diabetes Association recommend routine 50-gram glucose tolerance testing of all pregnant women between 24 and 28 weeks of pregnancy, while the American College of Obstetricians and Gynecologists recommends screening only for those older than 30 years. Those at high risk for gestational diabetes (history of macrosomatia or of stillborn pregnancy) should be screened with the 50-gram glucose tolerance test at the end of the first trimester. About 25% of women may be asymptomatic carriers of group B *Streptococcus*, and this remains the most common cause of neonatal sepsis in the United States. The protocol for minimizing this risk of neonatal sepsis includes screening all women for the carrier state at 28 weeks' gestation. Those women with cultures positive for group B streptococci are treated only if they fall into one of the following high-risk groups at the time of delivery: preterm delivery before 36 weeks of gestation, premature rupture of membranes more than 12 hours before the beginning of labor, prolonged rupture of membranes more than 24 hours before delivery, a history of other infants previously infected with group B streptococci, signs of amnionitis, or mother receiving immunosuppressant treatment. Earlier treatment does not provide prolonged protection, and treatment of uncomplicated term infants before delivery does not reduce the incidence of sepsis. Infants of mothers who are carriers but who did not receive treatment are monitored for sepsis but not routinely treated.

For one possible neonatal infection, less screening is now recommended. Serial cervical cultures for herpes simplex virus have not been useful for detecting those at risk for transmitting the virus during vaginal delivery. Current guidelines suggest confirming the diagnosis by culture of visible lesions at any time during pregnancy, then a careful examination during labor for any signs of active lesions. If none is present, vaginal delivery is indicated.

Some of the tests that attempt to detect fetal anomalies or congenital diseases offer hope for the prenatal treatment of the fetus. Others offer the option of therapeutic abortion or advanced preparation for a compromised fetus. For

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example, California requires the maternal serum α-fetoprotein screening be offered at between 15 and 20 weeks for neural tube defects. Ultrasonography and amniocentesis can confirm the anomaly and better clarify the severity. The parents then can make an informed decision regarding the management of the pregnancy. Maternal serum α-fetoprotein abnormalities can also provide clues for trisomy 21 and treatable problems such as gastroschisis. The risk of unnecessary intervention can be avoided if the α-fetoprotein screening is done with the cooperation of a dedicated coordinator, skilled ultrasonographers, and perinatologists. As another example, the screening of mothers at risk for the human immunodeficiency virus can anticipate the need for postnatal infection control precautions or can prepare the parents and physicians for the need for intensive attention to the newborn.

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Medication Misuse by the Elderly

THE misuse of medications by the elderly falls into two major categories. One is noncompliance with or non-adherence to a drug therapy regimen.This may occur in as many as a third to half of the elderly patients taking prescription drugs. The reasons found for noncompliance are poor communication with health professionals and impaired cognitive status. As many as 90% of cases of nonadherence to prescribed treatment can take the form of underadhering or taking too little medication. One study found that as many as 70% of the elderly patients may actually alter their intake of prescribed medication intentionally for a variety of reasons, including to attempt to minimize adverse effects. Drug misuse by the elderly can also occur as a result of a pursuit of symptomatic relief from unrecognized depression and from chronic ailments of advancing age. A physiologic dependency on tranquilizers, sedatives, and analgesics can easily develop in an elderly patient with undiagnosed depression. Therefore, the presence of depression should be carefully screened for when evaluating drug use in the elderly.

Another area of drug misuse by the elderly is the use of outdated medications or medications from other members of the family or neighbors. In one study of 334 low-income elderly and disabled persons living in a high-rise building, 75% of the subjects were found to be currently using prescription drugs and 82% were using nonprescription drugs. Respondents used an overall average of 4.5 prescription and nonprescription drugs regularly. About 51% of the interviewees stored one or more current prescription drugs and 67% stored one or more noncurrent prescription drugs. The average number of all medications per home was 8.4, whereas the average number of nonprescription medications was 2.6. In this study, 24% of the participants underused medication, 7% did not know the purpose of their medication, and another 7% shared their medication with other persons. In all, 6% used outdated prescription medication, and 4% overused their medication as prescribed. As shown by these statistics, the elderly usually do not consider nonprescription drugs to be medications and frequently omit these when mentioning what medications they are taking. There are also a lot of extra medications being stored at home that are not being accounted for on office visits to a physician.

In another study of 356 persons selected at random from the community, there were 125 cases of medication misuse. The most frequent types of misuse were inappropriate dosage, indications for use, or usage level. Most common classification of drugs misused are the psychotherapeutic drugs, diuretics, and cardiovascular drugs. There seems to be no association between the misuse of medication and gender, age, income, or education. Misuse, however, is positively correlated with the number of drugs being taken. There was significant difference in misuse between those persons who took psychoactive medications and those who did not. Persons who are taking psychoactive drugs are more likely to misuse drugs.

The problems of medication misuse by the elderly can frequently be addressed by better assessment and more drug information. Pharmacists can assume a more active role in patient education, and practitioners may consider providing community-based health and drug information education programs. Another way to address this problem is to make sure elderly patients bring all of their home medication into their physician's office when they are being evaluated. Another approach to assessing medication use to to do a home visit. It has been shown that home visits can be useful in providing additional information about compliance and drug use by the elderly. Finally, compliance can also be enhanced by clarifying written and verbal instructions, reducing the number of drugs, simplifying the drug dose schedule, and providing devices to assist patients with accurate self-administration.

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Pesticides in Food

THE recent national attention focusing on the issue of food safety prompted us to examine two studies of the actual occurrences of pesticides-related food contamination to see how well the incidence data corroborate some of the concerns.

In the first study, the Environmental Protection Agency (EPA) commissioned the National Research Council of the National Academy of Sciences to estimate the oncogenic risks from pesticides in the diet and to examine regulatory policies for oncogenic pesticides in raw and processed foods. The National Research Council selected 28 pesticides from the 53 determined or suspected by the EPA to be oncogenic and estimated the cancer risks from the diet. The estimated theoretical added lifetime risks for the daily consumption of some of these pesticides were greater than one in a million. When the National Research Council's report was released, there was a tendency to overlook or inadequately emphasize the theoretical nature of the risk estimates because it was assumed that pesticide residues were always present at the tolerance levels and that all the food crops had been treated with the pesticides. Actually levels of residues detected by monitoring programs are typically below the legal tolerances, and many crops are not treated with the pesticides in question nor do they show any detectable levels of residues. Therefore, these risk estimates should not be construed as true consumer risks, but they provide an index for ranking pesticides for regulatory attention.

In the second study, the National Resources Defense Council assessed the health risks of pesticide residues in food to preschool children based on an evaluation of two health effect end points, cholinesterase inhibition and cancer. One major assessment was that daminozide (trade name Alar), due primarily to it hydrolysis product, 1,1-dimethylhydrazine, which occurs in food, contributes to 85% of the estimated cancer risks. The ensuing public concern regarding daminozide residues in apples and processed apple products resulted in the temporary exclusion of these food items from school lunch programs in several cities. This action was not justified because there was no imminent hazard identified on the basis of the available data. The report brought the important and previously neglected issue of childhood exposure to the attention of the EPA, but the Natural Resources Defense Council failed to emphasize that food safety is not achieved by restricting the availability of fruits and vegetables or their intake. In this connection, it is of concern that a potential carcinogen was used in children's food for more than 20 years before the manufacturer was required to conduct adequate carcinogensis bioassays. Studies in the 1970s suggested that daminozide is carcinogenic in laboratory animals, and new data on 1,1-dimethylhydrazine are strongly suggestive. The issue of daminozide exemplifies the need for more stringent health testing of pesticides before they are permitted to be used. Use restrictions started in 1985, and the manufacturer is in the process of withdrawing the product.

The illegal use of pesticides has been responsible for several acute illness episodes in the western United States. In 1985 aldicarb residue in watermelons caused nausea, vomiting, diarrhea, profuse sweating, excessive tearing, muscle fasciculations,and bradycardia. The treatment in the most severe cases was to administer atropine sulfate.

Endrin, an organochlorine insecticide, caused five cases of poisoning in 1988 in Orange County, California. These may have been caused by deliberate tampering with a commercial product—a snack consisting of a corn tortilla wrapped around a meat filling sold in a sealed plastic bags. The symptoms included nausea, dizziness, and seizures. Since 1984, endrin is not registered for agricultural purposes or manufactured in the US, but supplies of the pesticide remain, and other countries continue to use and manufacture the chemical.

In summary, to our knowledge there have been no confirmed cases of acute poisoning from ingesting legally applied pesticides on food in California. On the other hand, health officials and physicians should be aware of signs and symptoms associated with pesticide overexposure and the existing reporting system for pesticide-related illness in order to assist in identifying cases, treatment, sources, and appropriate control and risk management measures.

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The Epidemic of Childhood Drowning

THROUGHOUT the western states, drowning surpasses motor vehicle occupant injuries as the leading cause of death of children ages 1 to 4 years. For every child who drowns, about two or three children survive severely brain damaged and an estimated eight to ten near-drowning victims are seen in emergency departments. Of the near-drowning victims treated in emergency departments, 80% are admitted to hospitals for further treatment or observation. With the widespread use of ventilators, intensive care units, and advanced cardiopulmonary resuscitation (CPR) techniques, many of the children who would have died before the mid-1970s now survive. As a result, there is a growing number of children who survive submersion events with severe neurologic damage due to anoxia but whose hearts and lungs recover. The actual size of the population is not known, but in California they constitute the largest group of children entering state institutions for long-term care with profound acquired brain damage. California alone spent more than $10 million in 1988 to care for these children.

Although children can and do drown in any body of water, the majority of incidents in this age group occur in residential swimming pools. Studies have shown that half of these drownings occur at a child's own house or apartment, 36% at the home of a friend, neighbor, or family member, and only 7% at other sites, including public pools. Children appear to be at greatest risk between the ages of 1 and 3 years. At this age, children cannot be made "water safe" through swim lessons because they lack sufficient strength, gross motor coordination, retention of learned skills, and judgement.

In the most common scenario, a child thought to be safe inside the house gains access to the pool while a parent or caregiver is momentarily distracted by the telephone or household chores. The whole event is silent, and the amount of time the child has been missing is unknown. Because neurologic damage occurs quickly with a lack of oxygen, prevention efforts have focused on constructing barriers to block access to pools, alarms to warn the caregiver, educating parents regarding the danger, and CPR training.

No one foolproof method of preventing access to a pool has been found. Thus, experts recommend that layers of protection be installed, including as many of the following as are feasible:

- Four-sided fencing that separates the pool from the house, is 1.5m (5 ft) tall, hard to climb but easy to see through, and with gates with self-closing, self-latching mechanisms that cannot be reached or operated by a young child;
- ASTM [American Society for Testing and Materials]-approved safety covers (covers not designed for safety pose additional hazards, and those not attached to the pool deck are dangerous);
- Door, window, and pool alarms; and
- Window and door locks.

The ultimate challenge is to develop protective technology that is both feasible and foolproof. In the meantime, physicians should counsel parents regarding the dangers of residential pools and the need for layers of protection, close supervision, and CPR training. The circumstances surrounding a submersion event should be noted in the medical record to assist prevention research and the recognition of causal patterns. Finally, physicians and the public health professionals should join with drowning prevention programs to see that four-sided fencing, pool safety covers, or both, are incorporated into standard building codes for implementation at the time of pool construction or the sale of a home.

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Injuries—The 'Neglected Disease of Modern Society'

INJURIES are the leading cause of death and disability of Americans between the ages of 1 and 44 years old. Each year more than 142,000 people are killed and 62 million others seek medical attention because of an injury. The cost of injuries, including medical expenses, lost wages, and property damage, was estimated at $143.4 billion in 1988.

While medicine has made great strides in combating infectious diseases, injury mortality has remained fairly constant. Until recently "accidents" were assumed to be caused by random or chance events and, as such, were considered outside the realm of prevention. We now know that injuries occur in predictable and regular patterns with identified agents and vectors. They are caused by human interaction with the environment and are strongly linked to a person's age and development. Motor vehicle occupant injuries affect all age groups and cause about half of all injury deaths and disabilities. In addition, injury mortality in the western states tend to cluster as follows: suffocation or choking and homicide deaths among infants; residential pool drownings among toddlers; pedestrian and motor vehicle occupant injuries among elementary school-age children; motor vehicle occupant and violent (homicide and suicide) injuries among teens; motor vehicle occupant, drug overdose, and violent injuries among adults; and falls, motor vehicle occupant, and suicide injuries among the elderly.

In recent years, the injury problem has begun to receive national attention, and the scientific discipline of injury control has been established. Injury research and control efforts have escalated, and a national lead agency has been established at the Centers for Disease Control. A number of effective prevention strategies have been identified as follows:

Injury Type	*Intervention*
Bicycle	Bicycle helmets
Burns	Smoke detectors, sprinklers, self-extinguishing cigarettes, flame-retardant sleepwear, water heaters preset to 49°C to 54°C (120°F to 130°F)
Choking	toy and food regulations, first-aid treatment of choking
Drowning	Four-sided fencing, pool safety covers
Falls	Window bars, hand rails, child-resistant barriers
Firearms	Gun control
Motor vehicle occupant	Car safety seats, seat belts, air bags
Motorcycle	Motorcycle helmets
Poisoning	Child-resistant safety caps, packaging in nonlethal doses
All injuries	Emergency medical services and trauma systems

The challenge before us is to implement these strategies through education, legislation, enforcement, and medical and public health leadership. In addition, we need to document in the medical record the circumstances of the injury event to determine causal patterns and prevention strategies.

Injury control should be addressed by a systems approach. Public health professionals should use vital statistics and hospital and trauma system data to define the problem within their region; mobilize community resources and persons to address problems identified; use environmental, legislative, and educational approaches for prevention; evaluate the impact of prevention efforts; and disseminate evaluation results to others to incorporate in program planning.

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The Preventive Use of Zidovudine in Asymptomatic HIV Infection

THE US Public Health Service estimates that between 1 and 1.4 million Americans are infected with the human immunodeficiency virus type 1 (HIV-1), the causative agent of the acquired immunodeficiency syndrome (AIDS). The inescapable conclusion drawn from studies of the natural history of HIV-1 infection is that in the absence of an effective intervention, the overwhelming majority of those infected will progress to have profound helper T-cell depletion and will die of AIDS.

Zidovudine (formerly azidothymidine; AZT) is currently approved for use for a narrow category of patients with advanced HIV disease. In August 1989, the momentum for expanding the indications for zidovudine use accelerated by a quantum leap. Two national placebo-controlled trials in mildly symptomatic and asymptomatic patients with HIV were modified short of completion by the National Institutes of Health AIDS Clinical Trials Group because of conclusive evidence for zidovudine's benefit and minimal toxicity. These results should lead to major changes in patient and physician attitudes towards HIV testing, T-cell monitoring, and treatment of this infection at all its stages. Before August 1989, the use of zidovudine in mildly symptomatic or asymptomatic HIV infection was an area of controversy among experts. In the months since the findings were made public, a new consensus is emerging.

The two studies enrolled two distinct, well-defined categories of patients with HIV disease, early AIDS-related complex (ARC), and asymptomatic seropositivity, respectively. Both studies showed the efficacy of using zidovudine in slowing the progression to symptomatic disease, AIDS, or ARC. The study in asymptomatic seropositive persons enrolled 3,200 volunteers and compared the use of placebo with that of zidovudine at two dose levels, 500 mg per day an 1,500 mg per day. For participants with CD4 (helper T-lymphocyte) counts of less than 0.5×10^9 per liter (500 per μl) in both zidovudine groups, the rate of progression over two years was cut by 50%. The adverse effects of the 500-mg-per-day regimen were minimal, the most notable being a 3% incidence of major anemia. While progression to symptomatic stages was not invariably stopped, the studies indicate that at least the short-term outlook for patients with asymptomatic or minimally symptomatic HIV disease can be dramatically improved. Information on the duration of the protective effect should eventually be available from long-term follow-up of these cohorts.

The US Public Health Service has estimated that 600,000 patients should be offered early treatment with zidovudine based on the findings of these two studies. Because of a reluctance to undergo HIV testing, many may be still unaware that they are infected. Most patients with HIV infection in this country became infected in the early 1980s. In view of the median interval of 9.5 years between the infection with HIV and the development of AIDS, the medical profession has a relatively brief window of opportunity to implement any intervention that slows the progression of HIV disease. The two studies prove that zidovudine, while not invariably effective, when administered at an early stage of disease can have a definite impact. The new data make it a particularly opportune time for health professionals to focus on HIV risk assessment and testing with all of their patients and to specifically review histories of sexual activity, substance abuse, and blood product transfusion. If physicians wait for the zidovudine package insert to be changed, they will deprive many patients of the opportunity to benefit from these new findings.

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Preventing Lead Poisoning in Children

THE current standard for blood lead concentrations in children is 25 μg per dl. Researchers throughout the world, however, have recently shown that a blood level of as low as 15 per dl during gestation and infancy is associated with subclinical neuropsychological impairments, particularly in verbal learning, with an average of four IQ points being lost.

Recent population-based surveys of children younger than 6 years living in older urban ares in Alameda and Los Angeles counties, California, indicate that many children are exposed to lead—blood concentrations greater than 25 μg per dl in 1% to 2% and greater the 15 μg per dl in 10% to 20%. Substantial lead contamination was found in indoor and outdoor paint in Alameda and Los Angeles county study areas (Los Angeles results unpublished) and in soil in the Alameda County area. An additional study is planned for Sacramento County, California. Indoor paint contamination occurs because many homes were built before the 1950 voluntary industry standard and the 1977 federal standard for lead in house paints. Soil contamination is from auto emissions, exterior paint, and industrial sources.

The California studies only tested paint from homes where paint was chipping or flaking. An additional hazard is present in homes where lead-based paint is in good condition but where renovation can lead to the spread of paint dust and chips into the home environment and exposure to children. In the past few years, several cases of such exposure have come to the attention of the California Department of Health Services; in most cases, the children involved were asymptomatic. Parents and contractors need to be educated about the proper techniques for removing paint that can prevent household contamination.

Additional lead hazards to children are posed by dangerous hobbies around the home (common ones are making stained glass and melting down lead shot to make fishing weights or model figures); ethnic fold remedies used for the treatment of diarrhea (used by such diverse ethnic groups as Hispanics, Southeast Asians, and South Indians); lead in drinking water from leaching from leaded solder, particularly from homes built in the past five years; and take-home exposures from parents who work in lead-contaminated workplaces such as radiator repair shops and smelters.

Public Health Approaches

The two basic approaches that have been proposed involve screening the children and then cleaning up the environment where lead exposure has been found in children or searching for possible environmental sources and regulating exposure.

Lead screening. Childhood lead screening programs are designed to identify elevated blood lead levels in children and investigate and remove lead from contaminated home environments. The US Centers for Disease Control recommend annual screening for children younger than 36 months living in older, dilapidated housing. Screening is not conducted in most of the western states.

The California Department of Health Services has undertaken educational efforts to provide physicians with the most-up-to-date information about lead exposure and to encourage them to increase their efforts to screen for lead poisoning. These efforts need to be increased. Access to information, however, is not the only barrier to physician involvement in lead screening. One barrier is motivation; in most cases no medical intervention is needed, other than identifying potential source(s) of exposure by history, giving nutritional guidance, and education parents. Possibly some form of incentive could be devised to motivate physicians to screen. The second barrier is technical: when screening for blood lead levels below 40 μg per dl, the erythrocyte protoporphyrin screening lest has a poor predictive value, and capillary blood lead specimens give a high false-positive rate. Providers do not routinely use venipuncture. Technologic breakthroughs in lead screening that would allow a more acceptable process of specimen collection would help overcome this barrier. In the absence of incentives, the development of new, more feasible technologies for screening, or a requirement that screening be done, it is uncertain what role physicians will take in addressing the problem in the future.

Environmental regulation. To address the problem of lead-contaminated houses, it is not necessary to first identify lead exposure in children. For example, a program could identify and decontaminate lead houses, using strategies to encourage owner participation. The costs are unknown, however, and the methods for lead removal need further study.

For other sources of lead exposure, additional regulatory and educational approaches could be undertaken. Lead is still used by the canning industry, with a voluntary standard for lead in solder. The phaseout of lead in gasoline has been only partially accomplished. Lead-based paint and solder are still on the market and are occasionally inappropriately used in homes. Laws restricting workplace lead exposures have a number of exemptions and are only partially enforced. Many household exposures could be prevented by education parents about lead in paint, pottery, ethnic remedies, and home hobbies.

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The Tuberculosis and HIV Connection

EVIDENCE suggests that clinical tuberculosis eventually develops in a high percentage of persons infected with both the human immunodeficiency virus (HIV) and *Mycobacterium tuberculosis*. Tuberculosis often precedes other opportunistic diseases in patients with the acquired immunodeficiency syndrome (AIDS), but tuberculosis-infected patients who survive the first episode of AIDS are at a high risk of clinical tuberculosis developing. This has contributed to the increase in the number of tuberculosis cases reported in the United States since 1984, which had been in a general slow decline for many years. In the United States, AIDS has been reported in as many as 12% of patients with tuberculosis.

The clinical presentation of tuberculosis in HIV-infected persons varies with the immune status, ranging from the more commonly recognized pulmonary apical cavitation in HIV-infected persons with minimal immune impairment to disseminated disease presenting with blood cultures positive for M tuberculosis in persons with advanced AIDS. A 5-mm or more reaction to tuberculin skin testing (purified protein derivative [PPD]) is seen in about a third of those AIDS patients with tuberculosis who are tested. The chest x-ray film often shows an atypical pattern that includes hilar and mediastinal adenopathy. Cavitation is present in less than 25% of cases, and diffuse reticulonodular infiltrations are frequently seen. M tuberculosi has been found in the sputum of some AIDS patients with normal chest roentgenograms. Extrapulmonary disease occurs frequently, often associated with pulmonary disease. Although Mycobacterium avium-intracellulare is frequently identified in patients with AIDS, acid-fast bacilli identified on staining from any specimen in high-risk HIV-infected person should be considered and treated as M tuberculosis until proved otherwise by culture.

The unusual patterns of tuberculosis in AIDS patients may make diagnosis difficult. Because tuberculosis is both contagious and treatable, every effort should be made to identify M tuberculosi in AIDS patients. The PPD skin test remains the most reliable test for detecting tuberculosis infection and should be done as early as possible in any person infected with HIV or diagnosed with AIDS. Any measurable induration should be considered as potentially significant, but a 5-mm or larger reaction is definitely positive. Any abnormality on a chest x-ray film in an AIDS patient should be considered suspicious for tuberculosis. Because of the high frequency of cases of extrapulmonary tuberculosis in patients with AIDS, any body fluid specimen—sputum, bronchial washings, cerebrospinal fluid, pleural fluid, ascitic fluids, urine—or lung biopsy specimen should be processed for acid-fast staining and culture during an evaluation for infection.

Antituberculosis medication should be given immediately whenever *M tuberculosi* is found or suspected in persons with HIV infection or at an increased risk for HIV infection. The recommended regimen is isoniazid, 300 mg daily, plus rifampin, 600 mg daily, and pyrazinamede, 1,500 mg daily. Ethambutol at a dose of 25 mg per kilogram of body weight daily should be added to the regimen when central nervous system or disseminated tuberculosis exists or isoniazid resistance is suspected. Pyrazinamide therapy may be discontinued after two months if the sputum smear results have converted to negative. The treatment of documented tuberculosis should be continued for at least 9 to 12 months or until the patient's cultures are negative for *M tuberculosi* at least six months. Tuberculosis in patients with HIV infection or AIDS responds well to antituberculosis chemotherapy. When tuberculosis patients with AIDS die, it is usually of other complications of AIDS and not the tuberculosis if they are receiving antituberculosis medication.

Preventative therapy should be given to any HIV-infected person or anyone at high risk for infection, regardless of age, who has a positive reaction to a PPD skin test. Actual disease should be excluded before starting the therapy. Preventive therapy in this circumstance consists of giving isoniazid, 300 mg daily, for at least 12 months.

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Opportunities for Preventing Woman Abuse and Battering

WOMAN abuse and battering is a public health problem of epidemic proportions. In a recent national survey, 16% of women reported physical abuse by their spouses; 6% reported severe abuse—that is, punching, kicking, choking, beating, and attacks with a weapon. In 1980 this resulted in 21,000 admissions to hospitals, 99,800 hospital days, 28,700 emergency department visits, 39,900 physician visits, and $44.3 million in medical costs.

Woman abuse is only infrequently identified by physicians. The use of simple nursing protocols with direct questioning has shown that 30% of all women presenting with injuries are battered. Only 10% to 25% of these are diagnosed by emergency department physicians, however. In a recent prospective study of women obtaining private and public prenatal services, 8% reported physical abuse during the current pregnancy and 15% in the past. Prenatal care providers, however, had never asked about abuse.

Early identification and intervention are vital, as violence tends to escalate, and relationship change becomes more difficult. Physicians from various specialities can play a role in prevention by maintaining a high index of suspicion and asking about abuse in a gentle and supportive way. The following findings, although nonspecific, may be clues to abuse: Obstetrics and gynecology: injury, divorce, separation, or suicide attempt during pregnancy; sexual dysfunction; persistent complaints; abortion, miscarriage, or premature delivery. Medicine or family practice: frequent visits with vague or unremitting symptoms; nonspecific clinical findings; requests for sleep medication or tranquilizers; abuse of drugs (legal or illegal) or alcohol; labels in medical record such as "hysterical" or "hypochondriac." Emergency medicine: trauma to head, face, breasts, abdomen, or both extremities; history incompatible with injury; previous trauma; coexistence of trauma with complaints of insomnia, anxiety, depression, alcohol or drug abuse; accompaniment by a male partner who is alcoholic, suspicious of medical personnel, or reluctant to leave the patient alone. Pediatrics: women with children having psychosomatic complaints; coexistent child abuse. Psychiatry: anxiety; depression; suicide attempt; alcohol or drug abuse or both, psychosis; and inability to "cope."

Because of the high prevalence of abuse and variable clinical presentation of victims, questioning should be done routinely. It has been shown that women not suffering abuse do not mind being questioned and battered women are grateful that someone has finally asked about abuse. Women should be assessed concerning the potential for lethal violence, offered support, assured that they are not alone, and provided information concerning community resources, such as shelters, counseling programs, and therapeutic programs for abusive men. Because of a ninefold increased risk of suicide, dispensing of pain or psychotropic medications should be minimized. Physicians should maintain frequent contact and remain available to provide support and information as needed. In this way, physicians and other health providers can play a key role in breaking the cycle of violence in American families.

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Physicians Deserve Our Trust

TIMOTHY B. NORBECK

Several newspapers in Connecticut, including the *Stamford Advocate,* and the Hartford *Courant,* recently printed a story of the report of a consumer advocacy group, the Public Citizen Health Research Group, which said that "states do 'a grossly inadequate job' of protecting the public from incompetent and abusive doctors"; the report further noted that "Connecticut ranks near the bottom in its rate of action against physicians."

Mr. Timothy B. Norbeck wrote the following article in response to the charge that these findings somehow reflected poorly on the profession in Connecticut and on the Department of Health Services Division of Medical Quality Assurance. Ed.

THE Connecticut State Medical Society is extremely proud of the high quality of care provided by the practicing physicians of Connecticut. That pride is not in any way diminished by the release of a report by the "Public Citizen Health Research Group." The report, which appeared in the June 29 issue of The Advocate, stated that Connecticut trailed other states in the number of disciplinary actions taken against physicians, as if more somehow would have better.

State health officials agree that figures in a report such as this can be misleading. Medical critics do not take into account the strong possibility that the low number of cases against Connecticut physicians may reflect a high quality of care provided state residents. After all, Connecticut is well known for the prestige of its physicians, hospitals, medical schools, teaching programs and research facilities. The Public Citizen Health Research Group report is flawed in other respects as well. For example, it suggests that 10,000 physicians are practicing clinical medicine in the state when, in fact, the actual number is about half that figure.

With four million Americans walking into physicians' offices every day plus countless other doctor-patient encounters in hospitals, it is only natural to assume that not all will achieve the desired outcome. Some, in fact, do reflect less than optimal care. Neither the Connecticut State Medical Society nor the county medical associations condone incompetence or negligence in the practice of medicine. We strongly support the diligent work of the Department of Health Services as well as the quality assurance efforts of hospitals and their medical staffs.

In 1984, the Connecticut General Assembly enacted legislation which required all physicians, hospitals or medical associations to report any physician who "is or may be unable to practice with reasonable skill and safety." In response this law, the Hartford County Medical Association, the New Haven County Medical Association, the Fairfield County Medical Association and the Connecticut State Medical Society entered into protocol agreements with the Department of Health Services in which their Physician Health Programs were recognized as "approved rehabilitation programs." The goal of such programs is rehabilitation consistent with the public safety. Contrary to the claims of the Public Citizen Health Research Group, the names of those in rehabilitation are, in fact, reported to the Department of Health Services.

If the Public Citizen Health Research Group is suggesting that medicine is an imperfect science, then they are quite correct, and no one would claim otherwise. With all our technological progress, even medicine will never be a perfect science. Perhaps part of the problem is unrealistic expectations of perfection. George Bernard Shaw once noted: "We have not lost faith but have transferred it from God to the medical profession." Flattering though that may be to physicians, the responsibility is too great, that faith is too short-lived, and unlike God, physicians are not immune to prosecution. They are indeed mortal beings subject to human weakness and error. Newspapers report daily on articles in medical journals by physicians uncovering the dangers of this or that mode of medical or surgical treatment or diagnosis. It is this very reporting by which the medical profession has made itself the most accountable of any in existence.

Just look at the record. Physicians are subject to review

TIMOTHY B. NORBECK, Executive Director of the Connecticut State Medical Society. Reprinted with permission of The Stamford Advocate, July 15,1990.

from state licensure agencies, medical societies, specialty boards, hospital credentialing committees, liability insurance company underwriting and claims review panels, hospital quality assurance and utilization review departments, and hospital morbidity, mortality and tissue committees—not to mention the regulatory scrutiny of federal agencies such as Medicare and the Drug Enforcement Agency and state agencies regulating prescriptions, office lab and X-ray facilities, Medicaid, and other matters.

There are, in fact, objective measures which reveal the quality of Connecticut's medical care to be among the very highest in the country. The Connecticut Peer Review Organization, reporting on quality of care issues arising from a whole year of reviewing Medicare hospital admissions, found significant adverse occurrences in fewer than 1 in 1,000 cases (0.067 percent), and milder quality lapses without adverse outcomes in fewer than 1.2 in 1,000 cases (0.118 percent). Thus our state's citizens can take justifiable pride and have confidence in the high quality of care accorded them by their physicians and hospitals. Of course, patients deserve nothing less than that.

Your doctor knows that such confidence is at the heart of the physician-patient relationship. Connecticut physicians are ever mindful of the thought expressed some 2,000 years ago by Publilius Syrus but still as true today: "Trust, like the soul, never returns once it is gone."

Infant Mortality by Marital Status of Mother—United States, 1983

From 1950 to 1987, the proportion of out-of-wedlock births in the United States increased sixfold, from 4% (1) to 24% of all births, respectively. In 1987, 17% of live births among whites and 62% of live births among blacks were out of wedlock (2). Because out-of-wedlock childbearing is associated with adverse pregnancy and infant health outcomes, increasing attention has been focused on out-of-wedlock childbearing as a maternal and child-health policy issue in the United States.

In 1960, the infant mortality rates for out-of-wedlock births for whites and for all other races were 33.0 and 51.2 deaths per 1000 live births, respectively. Rates for all live births for whites and for all other races were 22.2 and 41.4 per 1000, respectively (3). To update these data, the 1983 national linked birth-death file (4) (the latest data available at the time of analysis) was analyzed; the analysis was restricted to singleton live births to U.S. resident white (n=2,875,283) and black (n=546,949) mothers.

In 1983, 13% of singleton live births among whites and 59% of singleton live births among blacks were to unmarried women. Twenty percent of infant deaths among whites and 66% of infant deaths among blacks were among infants born to unmarried mothers.

For both whites and blacks, unmarried motherhood was associated with an elevated overall infant mortality rate, but the association was greater for whites (rate ratio [RR]=1.7) than for blacks (RR=1.3) (Table 1). The overall infant mortality rate was higher for infants born to unmarried mothers (13.1 and 19.6 per 1000 live births for whites and blacks, respectively) than for infants born to married mothers (7.8 and 14.6 per 1000 live births for whites and blacks, respectively). However, infants born to unmarried mothers <18 years of age had slightly lower infant mortality rates (14.3 and 20.7 per 1000 for whites and blacks, respectively) than infants born to married mothers in this age group (15.4 per 1000 for whites and 23.4 per 1000 for blacks). For mothers $\geqslant 18$ years of age, the out-of-wedlock/in-wedlock mortality rate ratios were >1 and generally increased with increasing maternal age.

The effect of marital status on infant mortality rates was greatest in the postneonatal period (28-364 days), where the variations in mortality by maternal age were larger. Postneonatal mortality for infants born to unmarried mothers was higher than for infants born to married women except for white mothers <18 years of age and black mothers <20 years of age.

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Fluconazole

TERESA LUBOWSKI, PHARM.D.

Introduction

FLUCONAZOLE is a new triazole antifungal available for both oral and parenteral use in the treatment of mucosal and systemic fungal infections. It is currently approved for the treatment of oropharyngeal and esophageal candidiasis, candidal urinary tract infections, candidal peritonitis, candidal pneumonia and cryptococcal meningitis.

Serum of Activity and Mechanism of Action

Fluconazole exerts its antifungal activity by inhibiting a cytochrome p450 mediated enzyme thereby depriving the fungus of ergosterol, the major sterol found in the cell membrane of yeast and fungi. Fluconazole has been shown to be efficacious in animal model infections of aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, cryptococcosis, and histoplasmosis.[1] The invitro activity of fluconazole against selected fungal pathogens does not correlate with activity in the invivo animal models. In general, the minimal inhibitory concentrations (MIC) values reported against pathogenic candida species are in excess of 100 mg/L.[2] This discrepancy in the invitro data may be a result of variability in testing methods and lack of standardized procedures. In addition, the newer antifungal agents often cause a gradual decrease of growth in the presence of increasing drug concentrations thereby making it difficult to determine precise MICs.

Pharmacokinetics

Fluconazole differs markedly from other azoles in its pharmacokinetic profile. Fluconazole displays dose dependent linear kinetics. It is a water soluble compound and is very well absorbed orally with a bioavailability of approximately 90%.[3] Peak plasma concentrations of fluconazole occur within one to two hours. Fluconazole has a volume of distribution that approximates total body water. Plasma protein binding of fluconazole is 11-12%, therefore, most of the drug is distributed in the unbound therapeutically active form. Fluconazole also has a prolonged serum half-life of 25-30 hours allowing once daily administration.[3] Cerebrospinal fluid concentrations of fluconazole reach 50-90% of the concomitant serum concentrations.[4,5] Approximately 80% of fluconazole is excreted unchanged by the kidney and the remainder is excreted in the form of metabolites.

Clinical Studies

Fluconazole has been the subject of a number of clinical trials in patients with oropharyngeal candidiasis, cryptococcal meningitis, and systemic yeast infections.

Meunier studied the treatment of oropharyngeal candidiasis with fluconazole (100mg/day) or ketoconazole (400mg/day) in patients with cancer.[8] Clinical cure was obtained in 15 of 19 and 14 of 18 patients with fluconazole and ketoconazole respectively. The relapse rate was similar between the groups but relapse occurred earlier in the ketoconazole group. Fluconazole was prematurely discontinued in two patients, one because of nausea and vomiting and one for increased alkaline phosphatase possibly attributable to the patient's underlying disease. In a randomized study of the treatment of oral candidiasis in 12 HIV patients, fluconazole 100 mg/day was compared to clotrimazole troches 10mg five times daily. The authors reported clinical resolution of 6/6 (100%) of fluconazole-treated patients and 3/6 (50%) of clotrimazole patients (p=.048). All of the fluconazole-treared patients remained disease free. Three of the patients who had initially responded to clotrimazole relapsed two weeks after therapy. One hundred percent compliance was achieved in the fluconazole group as opposed to only one patient in the clotrimazole group. There were no adverse reactions reported in either group.

The efficacy of fluconazole in the treatment of cryptococcal meningitis has been assessed by several investigators. In an open label trial, 22 AIDS patients with cryptococcosis were treated with 50-400mg/day of fluconazole for up the 64 weeks.[10] Seven of the patients had active culture-positive infections. Of these seven patients, four had a favorable clinical and microbiologic response. Fluconazole sterilized the cerebrospinal fluid (CSF) of two previously untreated patients as well as two patients who

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had failed amphotericin therapy. The remaining 15 patients in the trial had been successfully treated with amphotericin and were receiving fluconazole as prophylaxis. Relapse was prevented in 14 of 15 patients for periods of 11 to 64 weeks. Adverse reactions in this group of patients were mild and transient consisting primarily of an increase in hepatic enzymes in four patients. In a second open label trial, oral fluconazole 50-200mg/day was used as suppressive therapy of cryptococcosis in 19 AIDS patients.[11] Prior to enrollment in this trial all patients had received amphotericin B as primary therapy. Nine patients (47%) received successful maintenance therapy with fluconazole. Fluconazole was generally well tolerated. The most common adverse reactions were nausea, vomiting, and/or abdominal discomfort in 12 patients. Elevated hepatic enzymes were observed in five patients. Thrombocytopenia developed in one patient and resolved once fluconazole was discontinued.

As a result of the favorable clinical findings of fluconazole in the treatment of cryptococcal meningitis, two prospective randomized clinical studies comparing fluconazole to amphotericin B have been initiated and preliminary results have been reported. Larson et al[12] compared fluconazole 400mg/day to amphotericin B in the treatment of acute first-episode cryptococcal meningitis in 21 patients. Of the 14 fluconazole patients five (36%) were cured and eight (57%) failed. In the amphotericin treated patients five (57%) were cured and there were no reported failures. The authors reported a more rapid decrease in fungemia and conversion of CSF cultures in those receiving amphotericin B. A second multicenter randomized trial comparing fluconazole (200-400mg/day) and amphotericin B (>15mg/kg total dose) in acute cryptococcal meningitis is also ongoing.[13] Among the fluconazole patients 19 (45%) were considered cured as compared to 11 (48%) of the amphotericin group. The mortality rates of the two groups were also similar, 31% for fluconazole and 26% for amphotericin B. No significant difference has been reported to date.

Fluconazole has also been the subject of an open labeled prospective study of treatment of deep seated fungal infections.[14] Fluconazole 50-100mg/day was used in 17 non-neutropenic patients with fungal infections, including pneumonia, ophthalmitis, meningitis and fungemia. Clinical response was achieved in 82% of the patients. The therapeutic effect was greatest in esophageal infections caused by candida. The only patient with aspergillus infection failed therapy. A patient with opthalmitis responded initially, however, the infection relapsed three months after therapy was discontinued. The patient with fungemia due to *Candida glabrata* failed therapy with fluconazole. In two patients, mild and transient elevations of the alkaline phosphatase levels were possibly attributed to the use of fluconazole.

Adverse Reactions

Adverse reactions to fluconazole are relatively rare and mild. The most frequently occurring adverse effects are nausea, headache, skin rash, abdominal pain, vomiting and diarrhea. Abnormalities of hematologic, hepatic and renal function have been observed but only 1.3% of patients have been withdrawn from treatment due to these side effects.[6] Although serious hepatic reactions have been rare, fluconazole should be discontinued if clinical signs and symptoms of liver disease develop during therapy with the drug. The safety of fluconazole for use in children and pregnant or lactating women has not been established.

Drug Interactions

Fluconazole has been shown to increase the prothrombin time after warfarin administration in healthy volunteers. Although the increase was small (12%), patients receiving coumadin anticoagulants should be carefully monitored. In a placebo-controlled normal volunteer trial, fluconazole increased the area under the curve of phenytoin up to 75%.[6] Thus, phenytoin plasma concentrations should be monitored when it is administered with fluconazole. Fluconazole has also been associated with increased cyclosporine concentrations in kidney transplant patients.[7] This interaction appears to occur more often in renal transplant recipients than other transplant patients (ie, bone marrow) and in patients with impaired renal function.

Dosage and Cost

The recommended dosage of fluconazole for the treatment of oropharyngeal or esophageal candidiasis is 200mg on the first day followed by 100mg daily. For systemic candidiasis and cryptococcal meningitis the recommended dose is 400mg on the first day followed by 200mg daily. A maximum dose of 400 daily may be used based on the patients response to therapy. Since fluconazole has rapid and complete absorption when given orally, the intravenous dose is the same as the oral dose. Intravenous use of fluconazole is indicated in patients who cannot take enteral medications or have gastrointestinal malabsorption. The dose of fluconazole should be adjusted in patients with impaired kidney function according to the nomogram in the package insert.

Conclusions

Fluconazole is a new antifungal with a pharmacokinetic profile improved over currently available agents. It demonstrates comparable efficacy with ketoconazole in treating oropharyngeal candidiasis. In comparison with clotrimazole, it has shown greater efficacy and improved patient compliance. Its excellent CSF penetration makes fluconazole an attractive alternative to amphotericin B in the treatment of cryptococcal meningitis; open label trials have reported successful suppression of cryptococcosis with fluconazole. Its use as initial treatment of active crytococcal meningitis is less clear; two current trials comparing it to amphotericin B report conflicting results. Fluconazole may have role as a follow-up agent after initial treatment with amphotericin B in active infection. The experience with fluconazole in other systemic fungal infections consists of case reports with success mainly in candidal infections.

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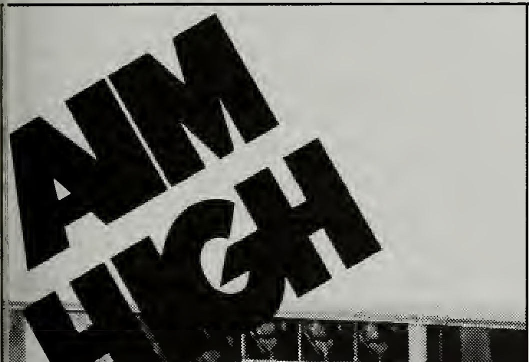

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Introduction

EPILEPSY is common. About 10% of all Americans will have at least one seizure at some time. Many people have one or a few attacks and then never have another one. For those with recurrent seizures, about 70% are satisfactorily controlled with antiepileptic drugs. Of the 150,000 people who develop epilepsy each year, 10% to 20% prove to have "medically intractable epilepsy." Many of these patients and their families have to deal with a chronic disorder that impairs the quality of life for all concerned.

Brain surgery may be an alternative treatment if antiepileptic drugs fail, and it is being used more often. Several centers have reported success, and increasing numbers of patients are being referred for surgery, including many children. Improved technology has made it possible to identify more accurately where seizures originate in the brain (epileptic regions), and advances in surgery have made operative management safer. As a result, investigators have estimated that 2,000 to 5,000 new patients in the United States might be suitable for operations each year, compared with the present annual rate of about 500.

Nevertheless, controlled trials have not been done, and there is disagreement among investigators about the choices and application of methods to evaluate patients for surgery, which procedures should be done, and how best to assess outcome. For these reasons, this consensus conference was organized.

There is no precise definition of intractable epilepsy. Among the considerations are seizure frequency, seizure type, severity of attacks, and impact on quality of life. Before seizures are deemed intractable it is necessary to be certain that the correct drugs have been used in the correct amounts. Complex partial seizures are more likely to be intractable than tonic-clonic or other common forms of epilepsy. In uncontrolled complex partial seizures, the frequency of seizures varies from fewer than one a week to five or more each day. The clinical manifestations also vary in different patients. Some are not apparent to anyone but the patient; others disrupt daily activities and are socially embarrassing. If a patient falls during seizures that occur only a few times a year, repeated injuries and trips to emergency rooms can make life miserable. Even one seizure a year may disqualify a person from having a driver's license. Disability is also influenced by the reaction of the patient's family, friends, teachers, or employers. All of these factors have an impact on what is judged severe enough to warrant consideration of surgical therapy.

There are other reasons to consider surgical therapy. For instance, repeated seizures may have adverse effects on the brain, leading to progressive cerebral degeneration and more severe clinical handicaps. Chronic use of antiepileptic drugs may cause toxic syndromes and may also have adverse effects on learning, scholastic achievement, development, and job performance.

On the other hand, surgery has risks and costs that have to be considered. Before a patient is accepted for surgery, it is necessary to be certain of the diagnosis and the adequacy of previous drug therapy. Evaluation for surgery includes several methods: video-monitoring, brain imaging, different kinds of electroencephalography, and neuropsychological tests. The best combination of these studies has yet to be defined. Investigators do not agree about the preoperative need to identify areas of the brain that control speech. Similarly, there are differences of opinion about the specific surgical procedures that produce the best outcomes for different kinds of attacks. Anterior temporal lobe operations and other cortical resections involve the removal of epileptic regions from the temporal lobe and other areas of the brain and are done for complex partial seizures. Corpus callosotomy involves the severing of connections between the right and left sides of the brain

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NIH Consensus Statements are prepared by a nonadvocacy, nonfederal panel of experts based on (1) presentations by investigators working in areas relevant to the consensus questions during a 1½-day public session; (2) questions and statements from consensus attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and the morning of the third day. This statement is an independent report of the panel and is not a policy statement of the NIH or the federal government.

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and is used for some types of generalized attacks; corpus callosotomy and hemispherectomy can be used for seizures with childhood hemiplegia.

This consensus conference was designed to address the following questions: (1) How should patients be selected? (2) What evaluation is necessary to localize epileptic regions? (3) What procedures are appropriate for specific epilepsies? (4) How should outcome be assessed? (5) Directions for future research—should a controlled trial be done? If so, for what seizure types?

To address these questions, the National Institute of Neurological Disorders and Stroke and the Office of Medical Applications of Research of the National Institutes of Health convened a Consensus Development Conference on Surgery for Epilepsy on 19-21 March 1990. After a day and a half of presentations by experts and discussion by the audience, a consensus panel drawn from specialists and generalists from the medical profession and related scientific disciplines, clinical investigators, and public representatives considered the evidence and came to the following conclusions.

1. How Should Patients Be Selected?

Patients with unsatisfactory seizure control often seek alternative care. The number or severity of the seizures may be unacceptable to the patient, family, or treating physician. Other reasons for referral include the results of diagnostic tests that may show a structural focal brain lesion, unsatisfactory psychosocial adaptation due to poor seizure control, unacceptable sedation, or other drug side effects. Such patients, especially those with persistent complex partial seizures and some types of generalized seizures, may be candidates for surgical treatment. First, however, these patients should be referred to an adult or pediatric neurologist for further evaluation of diagnosis and treatment.

Evaluation and medical treatment of these patients may take place under the supervision of a neurologist or in an epilepsy center that provides comprehensive diagnostic and treatment services designed for patients with intractable epilepsy. By "intractable" we mean that seizures have not been brought under acceptable control with the resources available to the primary care physician or neurologist.

To be effective and comprehensive, the staff of a center should include the following: neurologists with special training and experience in epilepsy; neurosurgeons with experience in epilepsy surgery; neuropsychologists; and personnel trained to deal with social, psychological, and psychiatric problems and rehabilitation for school and work. Ancillary neurodiagnostic personnel assessment must also be available, including closed-circuit TV and electroencephalography (EEG) monitoring telemetry; modern neurophysiological and EEG equipment; neuroimaging capabilities, including magnetic resonance imaging (MRI); and neuropsychological testing. Some centers also have positron emission tomography (PET), single photon emission computed tomography (SPECT), or other methods of evaluating cerebral blood flow and metabolism.

Before a patient is considered for surgery, evaluation should be sufficient to ensure the following:

- Nonepileptic attacks have been excluded and epilepsy is, in fact, present. Cardiogenic syncope, psychogenic seizures, and other nonepileptic states can closely mimic epileptic attacks.
- The epileptic seizure type and syndrome have been clarified. Primary and secondary epilepsies, partial seizures, and tonic-clonic seizures respond to different antiepileptic drugs and different surgical procedures.
- Diagnostic tests have been performed to define a metabolic or structural cause of the epileptic attacks.
- The patient has had a reasonable trial of the appropriate antiepileptic drugs, with adequate monitoring of compliance and the effects of the treatment.
- The patient and family have received detailed information about the specific seizure disorder, available drug treatments and side effects, and alternative treatments such as surgery. If, after this evaluation, seizures prove to be intractable or drug treatment is unsatisfactory, appropriate patients should be referred to an epilepsy center to be evaluated for surgery. Referrals should be made as soon as it is clear that medical treatment is unlikely to result in further benefit. Early referrals may prevent the development of chronic psychosocial and physical problems that result from uncontrolled seizures.

Coexisting disorders may affect the decision to operate; they may include severe psychiatric disorders, profound developmental retardation, or progressive neurodegenerative diseases. After the initial evaluation and a full unsuccessful trial of medical therapy, surgery may be considered. Patients with partial seizures and secondarily generalized seizures (attacks that begin locally and spread to both sides of the brain) are potential candidates. Secondarily generalized seizures may take the form of atonic, tonic, or tonic-clonic attacks. Patients with seizures and childhood hemiplegia may also benefit from surgery. Patients with the following seizure types are potential candidates: complex partial seizures of temporal lobe origin or other focal seizures; generalized, atonic, akinetic, or myoclonic seizures; and partial seizures with childhood hemiplegia.

2. What Evaluation Is Necessary to Localize Epileptic Foci?

Precise clinical, electrophysiologic, and imaging data are necessary to carry out surgical therapy. Neurological assessment is necessary to identify and exclude other forms of neurological disease. In all cases, EEG and MRI are used. Additional tests are often necessary for precise localization. The following electrophysiological techniques are used in establishing the diagnosis and focality of an epileptic disorder:

1. EEG is essential, sometimes with sleep deprivation or other activation techniques.
2. EEG monitoring with video (video-EEG) is used

widely in the evaluation of potential surgical candidates to exclude nonepileptic seizures and to define the electroclinical characteristics of the seizures. It is often used to establish and localize consistency and validity of the epileptogenic region.

3. For precise cerebral localization, other more or less invasive techniques are used in some cases to establish a high degree of confidence in the electrical localization. These methods include sphenoidal leads, subdural and epidural electrodes and grids, and depth electrodes placed stereotaxically. Decisions about the need for these procedures must be individualized.

Brain Imaging Techniques

Imaging techniques include x-ray computed tomography (CT), MRI, PET, and SPECT.

CT has a limited role in the investigation of partial epilepsy because MRI is superior to CT in demonstrating brain tumors, vascular malformations, and focal brain atrophy. The diagnostic value of MRI in visualizing mesial temporal sclerosis and atrophy is under study. MRI is useful postoperatively to assess the extent of surgical resection.

PET measures regional cerebral metabolism and blood flow. PET imaging has been quite successful in identifying the focus as an area of hypometabolism between attacks. This observation may be used in selecting patients with partial and secondarily generalized seizures for resective surgery. Because of the high costs and complexities of PET, this technology has been confined to a limited number of centers.

SPECT can also be used for functional imaging of the brain because it demonstrates regional cerebral blood flow, which is linked to cerebral metabolism and can therefore be used to identify the epileptic focus. SPECT uses conventional and readily available equipment and radiopharmaceuticals. These compounds can be used to study both ictal and interictal states. In the past decade, this relatively affordable technology has become widely available. More work is needed to determine whether SPECT is as sensitive as PET in localizing the epileptic regions.

Psychological tests are essential for the evaluation of varied cerebral functions, including memory and language. The intra-arterial amobarbital test is used to localize language function and to assess memory preoperatively.

These diagnostic methods should be available at specialized epileptic centers. However, the data are insufficient to determine which particular patients require the more invasive and detailed techniques.

Combining data from the major epilepsy centers would allow the development of a data bank or registry that should clarify many unanswered questions about the use of these diagnostic techniques.

3. What Procedures Are Appropriate for Specific Epilepsies ?

For 60 years, there has been continuous development of the surgical management of epilepsy. There have been many advances in the scientific understanding of epilepsy, in new technologies for localizing epileptic foci, and in methods for reducing operative risk. Neither randomized controlled trials nor large community-based clinical trials have been undertaken; nevertheless, several surgical approaches have been reported to be successful and rational in managing some types of intractable epilepsy. The data are not definitive and are primarily derived from single-institution studies. Surgery for epilepsy in patients with preoperatively detected neoplasms or vascular malformations depends as much on the nature and site of the lesions as on the seizure disorder.

The following discussion relates specifically to surgical procedures performed with the primary goal of alleviating a seizure disorder rather than removing a specific brain lesion. Data collected to date suggest that patients in three general categories are suitable candidates for epilepsy surgery: partial seizures of temporal or extratemporal origin, secondarily generalized seizures, or unilateral, multifocal epilepsy associated with infantile hemiplegia.

Patients with Partial Seizures

The largest group of surgical candidates comprises patients with complex partial seizures of temporal lobe origin. Preoperative evaluation identifies those patients with tumors or vascular malformations and can determine whether the epileptic focus is deep (in the amygdala or hippocampus) or superficial (cortical).

Appropriately directed, surgical resection of epileptogenic tissue has resulted in success rates of 55% to 70% of patients, when success was defined as no seizures (some auras may be present) for five years after surgery sometimes with some patients still taking anticonvulsant medication. In some patients, surgery also results in an improved psychosocial outcome, but this has not been studied adequately. Combined morbidity and mortality rates for surgery are below 5%. The charges for diagnostic evaluation and surgery vary from $25,000 in uncomplicated cases to over $100,000 in those who require extensive preoperative testing, with a median charge of $40-60,000.

Partial seizures of frontal origin and from other extratemporal sites may also be treated surgically when the clinical manifestations and diagnostic studies indicate an epileptic region in a resectable area. Appropriately directed surgical resection of epileptogenic tissue may result in improvement (as defined above) in 30%-50% of cases. The mortality rates are less than 2%, and the charges are slightly more than the cost of temporal lobe resection.

Patients with Secondarily Generalized Seizures

Some patients with generalized seizures may be candidates for surgical management. Specifically, patients with the Lennox-Gastaut syndrome or drop-attacks may be helped by section of the corpus callosum, a procedure designed to prevent rapid bilateral generalization of epileptic discharges. The procedure is most frequently recommended in patients who are prone to violent falls that often result in head injury. The seizure disorder usually persists postoperatively but seizures may become less frequent, less disabling, and less violent. Evaluation and selection of candidates have not been standardized. There is also variability of surgical technique, particularly how completely the corpus callosum is sectioned. Postoperative mortality is low, but significant complications may occur in as many as 20%. The charge for the surgery is often higher than for lobectomy because the procedure as done in some centers requires two operations, but the charge for the preoperative evaluation is often less.

Seizures Associated with Infantile Hemiplegia

In patients with intractable unilateral, multifocal epilepsy associated with infantile hemiplegia, hemispherectomy or callosotomy may be beneficial. These cases are rare, accounting for about 2% of all patients treated surgically for epilepsy. Success is measured not only by improvement in seizure frequency and type but also by improvement in behavior. Avoidance of complications (superficial cortical hemosiderosis and hydrocephalus) is a major consideration in the selection of surgical technique and has led to a current consensus for a "functional" hemispherectomy rather than one that is "anatomically complete." Success rates of 50% to 70% are balanced by combined mortality and morbidity rates that, in the past, reached 50% with anatomical hemispherectomy. Initial charges are similar to those for callosotomy but are increased by subsequent charges of dealing with late complications.

4. How Should Outcome Be Assessed?

Most studies that have assessed the outcome of either medical or surgical treatment of epilepsy have emphasized a single measure: seizure elimination or reduction in frequency. This measurement of seizure frequency needs to be clarified. For example, is a 50% reduction in a person who has two complex partial seizures a week equivalent to a 50% reduction in a person who has two seizures a year? We recommend the use of standardized methods to collect information about the frequency and kinds of seizures the patients are having.

Although we recognize the importance of seizure frequency, we recommend that future studies should use "general measures" of outcome that would take advantage of validated and quantative methods to assess the quality of life and health status of individuals. This could be achieved by a standardized survey to assess the following: short-term surgical mortality and morbidity or complications (e.g., death, paralysis, or infection in the postoperative period); physical health (symptoms, functioning, role activities, sleep-wake cycle, and mobility); mental health (psychiatric diagnoses as well as symptoms such as anxiety or depression); neuropsychological assessment, including cognitive functioning and memory, both verbal and nonverbal; social health (personal interactions, employment, sexuality, driver's license, and community interactions); and general health (health perceptions, including fear of death and pain, life satisfactions, and energy). Evaluation of children should include assessment of developmental progress and school performance.

To evaluate each of the above, we recommend using general measures of health status and quality of life so that patients with epilepsy can be compared to patients with other chronic conditions. Epilepsy is a unique condition and we also recommend that, in addition to the general measures, supplemental information should be collected about the specific aspects of the quality of life of patients with seizures, as discussed above. This information should be gathered from family members in addition to the patients themselves. Because epilepsy affects the whole family, the family's well-being should be part of the assessment.

The assessment of any treatment of epilepsy must include analysis of the economic impact on patients, families, and society. Economic impact includes expenditures on medical care directly (surgical and hopitalization costs, medication costs, costs of allied health personnel) as well as indirect costs such as contributed care by family members and whether a patient's income and productivity are affected positively or negatively in the future.

Assessment must be done repeatedly for several years. Data from treatment centers should be pooled to achieve statistical power sufficient to test the efficacy of treatment, as assessed by the multiple outcome measures.

We recognize that individuals will emphasize different outcomes. Some may be more concerned with the reduction in seizure frequency; others may be more concerned with the effect of treatment on memory or social function. Evaluation of any therapy for intractable epilepsy must explictly consider these patient preferences.

For all of these considerations, there is a need for a standardized method of data collection so that results from different treatment centers can be combined and compared.

5. Directions for Future Research—Should a Controlled Trial Be Done? If So, for What Seizure Types?

A. The panel is impressed that surgery is beneficial for selected patients, but the optimal timing of surgery is not known. Because of current referral patterns, patients considered for temporal lobe resection tend to have had uncontrolled (intractable) epilepsy for 10 to 20 years. We therefore recommend a controlled trial of early versus late surgery to determine whether early surgery or optimal medical treatment followed by later surgery of patients with complex partial seizures will result in better health status and quality of life and may prevent additional brain damage or chronic social disability.

B. Investigators differ in the selection of tests for preoperative evaluation. In particular, it is not known when more extensive diagnostic tests are needed, including ictal surface EEG recording, invasive intracranial electrode recording, PET, or SPECT. A program should be developed to assess the values of these tests, and should include the development and evaluation of algorithms. This would require standardization of definitions, data collection, and central analysis of the data.

C. We recommend development of an outcome assessment method that combines validated measures already used to assess general health status and function in a population of patients with other chronic conditions, with special items that are sensitive to the unique characteristics of people with epilepsy and those close to them, as described in the answer to question 4.

D. We recommend that psychiatric and behavioral functions be systemically assessed before surgery and during follow-up to determine whether there are specific contraindications to any particular surgical procedure and whether these procedures subsequently affect behavior.

E. In temporal lobe surgery for partial seizures, standard and "tailored" resections are used by different groups but the results are apparently similar. The circumstances in which each technique is maximally effective should be clarified by standardized data collection including documentation of extent of surgical resection and multivariate analysis so that an appropriate trial may ultimately be planned, if needed.

F. Because epilepsy surgery now may be used more often in children than in the past, we recommend additional studies to determine the effects of uncontrolled seizures and antiepileptic drug therapy on the developing brain. These studies might include, but not be limited to, evaluation of sequential neurodevelopmental assessment, anatomic and metabolic imaging procedures, cognitive-linguistic-academic achievement in school, and psychological adaption of the child and family.

G. Surgical treatment of epilepsy might not be needed if we knew more about ways to prevent brain injury or if we had more effective and less toxic anticonvulsant drugs. It is therefore necessary to support fundamental research in the basic sciences of epilepsy: developmental neurobiology, neural science, cellular pathology, neuropharmacology, and preventive epidemiology.

Conclusion

- Most epilepsy surgery is performed by teams of committed physicians at sophisticated medical centers. The number of operations is increasing rapidly.
- As currently used, surgery for intractable epilepsy is capable of stopping seizures or reducing their frequency. Effects on overall health status and quality of life have not been adequately studied.
- Several different diagnostic studies and surgical techniques have been used but do not clearly differ in effectiveness.

Recommendations

Before surgery is performed, there are three absolute requirements. First, the diagnosis of epilepsy must be ascertained. Second, there must have been an adequate trial of drug therapy; that is, the correct drugs used in the correct dosage, carefully monitored for an appropriate time. Finally, the electroclinical syndrome must be defined.

As demand for surgery grows and it becomes available at more hospitals, quality of care must be maintained. Surgery should be performed at hospitals equipped with modern technology and staffed by multidisciplinary teams capable of preoperative diagnosis, selection of medical and surgical treatments, comprehensive postoperative evaluation, and ambulatory rehabilitative care. Rehabilitation should include the transition of patients to a seizure-free or almost seizure-free life-style with respect to psychological and social adjustment, education, and vocational training.

Physicians in any center or independent hospital that offers surgery for epilepsy should agree to use standardized data collection for all patients. The data should be maintained in a central registry, with respect for confidentiality. The data should include demographic information, diagnosis, clinical history, results of preoperative evaluation, and outcome assessment of quality of life and health status for at least five years. Outcome information should be provided to patients considering surgery so that expectations about the benefits and risks can be discussed and assessed.

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Home Care in the 1990s

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Home care is a rapidly growing field that is beginning to attract greater physician interest and participation. Cost-containment pressures have led to reduced institutionalization in hospitals and nursing homes and to more patients, both acutely and chronically ill, being cared for in their own homes. Undergraduate and graduate medical education programs are developing home care curricula, and academic medicine is beginning to develop a research agenda, particularly in the area of clinical outcome measurements. Medical care in the home is highly diversified and innovative. The areas of preventive, diagnostic, therapeutic, rehabilitative, and long-term maintenance care are all well represented as physicians develop new practice patterns in home care.

HOME care is currently one of the most rapidly growing areas of the health care system. While hospital beds and utilization have declined and nursing-home beds have increased by 2% annually, the home health industry growth rate has been 20% per year for the last 5 years.[1]

Traditional physician house calls had been decreasing steadily since the 1940s, and many physicians saw themselves as peripheral to the new home care field, unfamiliar with the jargon, techniques, and equipment[2] and uncomfortable when asked to sign certifications of the need for home care services. This situation began to change with the cost-containment pressures of the 1980s as more acutely ill patients were cared for at home under much closer physician supervision than in the past. Surprisingly, recent surveys of primary care physicians (from the fields of family practice, general medicine, and internal medicine) have shown that 53% to 82% of them make house calls.[3]

The growing demand for greater physician involvement in home care is reflected in the recommendations for including specific home care training in accredited family practice and internal medicine residencies. Home care clinical and administrative experiences are a requirement in the new geriatric fellowship programs. Undergraduate medical school programs are beginning to add home care rotations.

Definition

Home care can be defined as the provision of equipment and services to the patient in the home for the purpose of restoring and maintaining his or her maximal level of comfort, function, and health.

Equipment that has been adapted especially for home care ranges from blood glucose monitoring for the diabetic through computerized total environments for the disabled and mini-intensive care units with ventilators, central venous lines, and long-distance telemetry for the acutely ill. There is an evergrowing range of assistive devices to help the patient overcome impairments in speech, vision, hearing, mobility, and cognition. Finally, there are devices to improve communication, socialization, and recreation for the homebound, from specialized telephones and computers to talking books and captioned television.

The myriad services that may be necessary in the home are provided by physicians; nurse specialists; registered and licensed practical nurses; physical, occupational, and speech therapists; medical social workers; nutritionists; respiratory therapists; laboratory technicians; vocational and educational rehabilitation personnel; podiatrists; pharmacists; dentists; psychologists; audiologists; optometrists; home health aides; personal care assistants; homemakers; chore housekeepers; volunteers delivering "meals-on-wheels," friendly visitors; and home construction workers for the building of ramps and other structural changes. The primary care giver, however, is usually a member of the family.

Medical care at home can be preventive, diagnostic, therapeutic, rehabilitative, or long-term maintenance

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From the Council on Scientific Affairs, American Medical Association, Chicago, Ill.

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This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of June 1989.

Dr. Joanne Schwartzberg is medical director of Home Health Service of Chicago North, a not-for-profit home care agency, and is funded in part by a grant from Caremark Inc, an affiliate of Baxter Healthcare Corporation.

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care. Each area has many historical models as well as modern innovations.

Preventive Care at Home

Many primary care physicians see preventive home care as an extension of their office practice. Thus, the home care program for an ambulatory patient with osteoporosis would be planned with the goal of preventing falls and fractures and could include home safety equipment such as transfer benches and grab bars; patient education and counseling on safe environments, including adequate lighting, stair rails, and the removal of scatter rugs; joint protection instruction and assistive equipment for daily activities; and a physical therapy program to improve gait and balance.

Preventive care is also a part of the treatment plan of an acute episode of illness, directed at preventing further complications and restoring the patient to the level of function prior to the acute illness. Thus, the home care program for a patient following an acute myocardial infarction might include daily monitoring to anticipate and hopefully prevent or ameliorate the development of cardiac arrhythmias, recurrent infarction, hypotension, congestive heart failure, and the many other possible complications of an unstable cardiovascular system. Continuous evaluation of the drug therapy program includes in-home testing for blood levels of the different drugs and electrocardiograms or rhythm strips (frequently transmitted via telephone lines) as well as careful elicitation of the patient's symptomatic reactions to the treatment. Because the burden of care falls on the patient and family, attention to family dynamics, the need for behavioral modification, and patient education and counseling to enable compliance with the medical plan of treatment is an essential part of preventive home care. After stabilization,cardiac rehabilitation, including physical therapy, helps determine the maximal level of functioning, the prevention of invalidism, and the maintenance of health and well-being.

Diagnostic Care at Home

Although most physician interactions with their patients have a diagnostic component, under current cost-containment pressures the traditional diagnostic workup has been pushed out of acute-care hospitals into outpatient settings, physicians' offices, and the home.[4] Although the outpatient setting may be an improvement on the hospital setting for diagnostic examinations for the majority of patients, for the frail elderly and chronically ill the outpatient process can be physically, emotionally, and financially difficult. Patient stress may obscure accurate diagnoses under these conditions.

It is not surprising that home visit assessments following assessments in a physician's office revealed an average of two new problems per patient and a range of one to eight new recommendations for the medical treatment plan of care in a recent study by Ramsdell et al.[5] Twenty-three percent of the newly found problems could have resulted in death or significant morbidity. Thirty percent of the new problems, identified only at home, were medically related, 38% were psychobehavioral, and 36% involved serious safety hazards.

As more medical school, residency, and fellowship programs are developing home care educational curricula, the reports and evaluations of these home care rotations emphasize the improvement in diagnostic skill and sensitivity.[3,4,6-9]

The diagnostic value of home visits was recognized in the 1988 National Institutes of Health Consensus Development Conference Statement on "Geriatric Assessment Methods for Clinical Decision-making,"[10] which stressed the importance of home visits to evaluate functional status and environmental characteristics—two of the five major diagnostic areas of a comprehensive geriatric assessment.

Koenig[6] has selected some useful indicators for diagnostic visits in the home:

1. Sick patients with multiple medical problems and mobility difficulties who are taking multiple medications; any patient with recurrent falls.
2. Patients with multiple chronic illnesses and suspected interacting psychosocial problems.
3. Sick patients who are responding poorly to medical therapy.
4. Chronically ill patients who are difficult to relate to and seem unsatisified with their care.
5. Terminally ill patients who wish to die at home.
6. Homebound disabled patients whose caretakers are fed up, frustrated, or reaching their tolerance limits.
7. Suspected cases of patient abuse.
8. Older persons with known significant medical problems who refuse to be seen in the office.
9. Recently bereaved homebound persons with coping difficulties.

Physicians who see many patients at home begin to practice a different style of diagnosis than that traditionally taught and practiced in hospital settings. Portnow[11] and Bernstein[2] describe this as "stepwise" diagnosis as opposed to the pressurized search for the "definitive" diagnosis.

Hospital protocols and standards of care attempt to arrive at conclusive diagnosis within the shortest period of time, subjecting the patient to the full battery of possible tests almost simultaneously. Some of the tests may not be necessary if the physician can tolerate the uncertainty and follow a modified plan of serial evaluative tests and a trial of treatment that is, in itself, diagnostic. This stepwise diagnostic approach is characteristic of good medical practice in an ambulatory setting; in the home care setting, with the support of home nursing staff, it can be applied to seriously ill patients who were previously seen only in the hospital.

A measured pace of diagnosis and trial of treatment is particularly appropriate for the elderly patient, whose response to treatment is often slow. This approach, geared to patient comfort as well as safety, may avoid overreaction and overtreatment.

Sophisticated medical diagnosis at home can be provided through the physician mobile medical van services being developed around the country.[12] A computerized emergency room in a van[13] has the capacity to convert x-ray film to digitized audiovisual signals that are transmitted via modem to the referring physician's office within 30 minutes from the time the "mobile" physician arrives at the patient's home. Full laboratory, pharmacy, and therapeutic services such as casts and traction can be available more rapidly through this van than through the usual ambulance/emergency room route.

From the patient's point of view, home care has always seemed the most efficient, effective, and least traumatic form of medical care. The perceived inefficiencies of home diagnosis from the physician's point of view are being balanced by more complete diagnoses, more appropriate diagnosis/treatment plans, easy availability of home laboratory services, and the full range of multidisciplinary support services offered by home health agencies.

Therapeutic Care at Home

Virtually every treatment modality in the hospital that can be made portable can be provided in the home. Some patients now are discharged directly from intensive care unit to home, trailing behind them portable pumps, central venous lines, ventilators, and so forth. One of the most rapidly growing areas in medical technology is the design and production of equipment specifically for use in the home. The equipment used in the hospital for intravenous (IV) therapy (IV poles, piggybacked glass bottles, pumps, steel needles, arm boards, and restraints) all seem old-fashioned when compared with the streamlined, simplified, tamperproof home IV products that make it possible for solutions in lightweight plastic containers to be tucked into pockets while delivering consistent dosages not dependent on gravity or the manual dexterity of the patient. Patients receiving IV therapy at home are not immobilized as they are in the hospital. Indeed, many return to work while receiving therapy. Tiny computerized pumps allow cancer patients to safely control their own dosage of continuous IV or subcutaneous narcotics. Babies who use ventilators crawl around their own living rooms; older children tuck their portable ventilators under the wheelchair when they go to school.

Programs have been developed not only to deliver needed home medical supplies, but also to handle the collection and safe disposal of used, infectious, or hazardous materials.[14]

Hospital treatments from debridement of decubiti to prosthetic training to bed baths can be provided in the home under the direction and supervision of the patient's physician. However, the physician, who can monitor hospital care on-site daily, has much more difficulty monitoring home care over the telephone and through the mail.[15] Home visits by the primary physician may be medically necessary and appropriate for patients with unstable medical conditions or technologically complex care.

As with technological equipment, the provision of professional therapeutic services in the home is being streamlined and individualized in ways not yet possible in the less flexible hospital setting. For the appropriate patient, nursing services may be provided one-on-one for 24 hours a day (for example, for the complicated care of a ventilator patient) down to half an hour per month (to change a Foley catheter). Whereas nurses in the hospital make rounds three times a day on all patients, the home care rounds are individualized from daily visits for dressing changes or other treatments to three times a week or once a week, depending on patient and family need. The determining factor in the frequency of visits is not only the patient's condition but also the ability of the patient and family to learn how to provide the needed care themselves. The goal of home care is to make the patient and family self-sufficient.

The involvement of patients and families in the treatment programs is one of the factors that lead to the enhancement of therapeutic effectiveness that is a hallmark of home care.

Rossman,[16] in citing instances of unexpected improvements in home care patients, credits the "positive and ameliorative psychologic factors" in the home setting. Increased motivation and patient control and decreased anxiety and depression can "alter an illness trajectory." A careful study of home vs hospital care for stroke patients showed that the home program resulted in a quicker return of function and a reduction of mortality.[17] Other studies have demonstrated improved clinical outcomes following home care.[18,19]

One area in which the enhancement of medical care in the home can be seen most clearly is in hospice care. The goals of hospice programs, with their emphasis on palliative care, on patient comfort and patient choice, on emotional and spiritual as well as medical support, and on death with dignity, are extremely difficult to integrate into the philosophy and methodology of modern hospitals. The home is definitely the superior therapeutic environment for the majority of hospice patients.

Rehabilitative Care at Home

A broad range of rehabilitation services in the home can be streamlined and individualized based on the patient's condition and the abilities of the patient and family to participate in and supplement care.[20] There is at least one program that provides intensive rehabilitation in the home (avoiding any need for a stay in a rehabilitation hospital) by sending physicians, rehabilitation nurses, and physical, occupational, and speech therapists into the home on a daily basis.[11] Most home rehabilitative care follows hospitalization. Many patients appear to progress as rapidly at home receiving only 3 hours of physical therapy a week as they did in the rehabilitation hospital with daily or twice-daily therapy. This goal can be achieved by the use of carefully graduated home programs when the patient and family are motivated to follow through with the therapeutic exercises. The barriers on streamlining the therapy program are the complexity of the program and the educational and psychological limitations of the patient and family. There are may studies that stress the importance of the family and social support network in the functional recovery of elderly patients.[21-23]

The goal for rehabilitation therapy is not merely independence at home, but reintroductions into the socioeconomic life of the community.

The interdisciplinary team planning for the disabled child works toward the goal of the child's entrance into a school program, into extracurricular activities, and eventually, at adulthood, into a job and normal productive life.

Vocational rehabilitation is an important part of home rehabilitation programs and serves as a liaison to community-based job training and job placement programs. One new group of home care patients for whom adaptive work strategies and retraining programs are particularly important are patients with AIDS.[24]

The rehabilitation program for the elderly patient often gets diminished by "ageism" into the acceptance of minimal independence in the home as sufficient, rather than the traditional goal of maximum functional capability. There is no reason not to offer the elderly patient a full therapeutic program that stresses community ambulation and mobility (including driving a car). The physiological and psychological benefits of mobility and socialization more than offset the additional cost.

Long-Term Maintenance Care at Home

Chronically ill and disabled patients have a continuing need for medical and supportive care to maintain their maximum functional level of activity. In addition to the monitoring/diagnostic services of the physician, supportive care services are needed; these are provided by a variety of people from family members and friends to home health aides, homemakers, housekeepers, etc. Many patients also need monitoring, reinforcing, and educational upgrade visits from therapists and nurses.

Physicians who maintain only office-based practices, requiring the patient to get out of the house to see them, often augment their practice by the use of home health nurses to monitor the patient between office visits. Increasingly, physicians are choosing to make home visits to selected patients whose mobility is seriously impaired.[4,25]

Consistent medical management may stabilize or prevent the progression of various chronic conditions, but the patient remains frail and impaired and unable to independently manage the various activities of daily living. Approximately 85% of the patients who need long-term supportive care receive it from their families and friends. Only 15% receive formal paid services from any of the various community resources.[1] The financial, physical, and emotional burdens on the care givers can be very great,[26] and there is need to develop programs to strengthen the informal support system through provision of respite care, counseling, service credits, and possibly tax incentives.

The explosive growth of the elderly population that we are currently witnessing, with those over 85 being the most rapidly expanding group, leads to predictions that long-term maintenance home care will be the largest area in the home care field. Although 20% of those over 65 can be considered "frail" elderly who experience functional limitations secondary to chronic disease processes, 46% of those over 85 who live in the community fall into the frail elderly grouping and are therefore candidates for long-term maintenance home care.[27]

Children and adults who are disabled (whether from congenital problems, neuromuscular disease, or posttraumatic injuries) may require supportive care assistance as well as intermittent nursing and physical therapy services to ensure maintenance of their maximum functional capabilities.

The need for assistance with activities of daily living such as eating, dressing, bathing, toileting, transferring, and walking is often through of as a "social" need, not a "medical" one. Yet, the provision of these services, either by family members or a paid community worker, is crucial to the health and well-being of the patient.

The first attempts at studying community-based long-term care have led to contradictory findings as to nursing-home or hospital use or total costs,[28] although most studies stressed the "quality of life" improvement and satisfaction reported by the patients. Studies by Hughes et al[29] on a carefuly selected "target" population of frail elderly show that provision of long-term care at home significantly lowers the risk of permanent admission to sheltered or intermediate-level nursing homes (but not to skilled nursing homes). There was no difference in mortality rates between comparison group of frail elderly who received meals-on-wheels and traditional medical intervention and the study group who received the long-term home care program over the 4-year evaluation period. However, there was a surprise finding of improved cognitive functioning in the home care group after 9 months, which was continued through the 48 months of the study.[30] The study concluded that the home care program (which consisted primarily of visits by home health aides with occasional visits by social workers, nurses, and physical and occupational therapists), when seen as a "treatment," had a "beneficial effect on cognitive status." The group receiving home care services also showed a greater amount of social contact with friends and better physical and mental health assessment scores. This study documents the "enhancement of care" that is so often referred to as the major benefit of home care.

Provision of supportive care can thus be seen as "enhancing" the therapeutic program, but is it medically necessary for the success of the medical treatment plan of care? One of the few studies addressing this issue was conducted by the Wilder Foundation[31] when they followed a group of frail elderly patients who had been receiving home health aide services through the Alternative Care Grants program in Minnesota. This was a state program, funded through Medicaid "waivers," that identified patients "at risk" of nursing-home placement via preadmission screening and then provided home care as an alternative. In 1986 a shortfall of available funds forced Ramsey County to decrease its alternative care service, which was accomplished by tightening financial eligibility requirements. Two hundred eighty-one clients were dropped while 178 were maintained in the home care program. All 459 clients were followed in the study. After 8 months, the group that no longer received home care services had twice as high hospitalization and mortality rates as those who continued to receive the home care program. This study highlights the medical necessity of supportive care.

Conclusion

Home care is an increasingly important aspect of medical practice. In this continuum of health care settings, little attention has been paid to the physician's role in this multifaceted arena. Practicing physicians in many specialty areas currently interact with a wide variety of home care providers; most of them spend from 5% to 10% of their time, but some spend up to 100% of their time, in home care.

More clinically oriented research is needed on patient care in the home before we can know with any assurance what interventions are most effective and appropriate. Until now, most of the research done has concentrated on cost rather than clinical practice and outcome. As academic medicine becomes more involved with home care, we can expect to see the research emphasis shift into the needed clinical areas. As practicing physicians become more involved with home care, we can expect to see even greater innovation and growth in this new/old field of medical practice.

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Dam the Blood

E. TREMAIN BRADLEY, M.D.

WHEN external bleeding occurs, it is often alarming, always disturbing, disruptive, messy, and certainly a nuisance. Only if significant arteries have been opened need "pressure points" or tourniquets be applied to counteract the force of the cardiac contractions. Convenient, prompt, and effective control of venous bleeding depends likewise, of course, upon the intravenous pressure.

A newcomer to town had a nightmare, tried to climb out of a window. His wife held him back. But he broke the panes and grabbed the struts in between and pushed his arms through. The jagged pieces of glass remaining tore his arms unmercifully before he finally woke up, bleeding profusely. I was called—in bed, asleep, two miles away. My instructions on the telephone to his wife were to have him lie flat on his back and hold both arms straight up. By the time I arrived eight minutes later, blood was clotted over most of both arms, but there was *no* active bleeding. He was cleaned up and sewn up in the emergency room.

Why did the flow cease? There was almost no resistance to the return flow of deep venous blood to the heart, so the more superficial veins did not fill, and did not bleed. An observation: note the engorged veins in the back of your hand, then slowly raise the hand and watch the veins empty and collapse—usually about eight inches above cardiac level.

Yes, direct pressure will also stop venous bleeding, but it is difficult to apply direct pressure to multiple sites. Routinely following venipuncture, pressure with gauze is applied and then a Band-Aid. In view of my distaste for adhesive tape, I just raise my arm high for three or four minutes and never develop a hematoma or ecchymosis.

What about nose bleeds? These are rarely of arterial origin, coming rather from the plexus on the lower part of the septum. Packing the nostril certainly stems the flow, but is uncomfortable and removal often starts up the flow again. Having been cursed with this annoyance on the average about three times a week for most of my life, I learned two things. First, if you tip your head back, the nasal chamber fills with clot which extends on back into the nasopharynx. Undesirable! Therefore, tipping the head slightly forward allows the blood to run out, into the sink, or onto the ground. With water available, a little in the palm of the hand can rinse the tip of the nose and the vestibule just inside, care being taken not to sniff up to the site of bleeding. A water-cooled hand applied several times to the bridge of the nose *may* help constrict the vessels. Anyway, it feels good.

Second, a negative venous pressure can be produced—with the torso upright—by long, slow continuous inhalations alternating with brief, quick releases through the mouth and immediately starting the next inhale. Having rinsed the nose and vestibule, a finger is pressed gently on the side, opposite the site of bleeding. After three or four minutes, the finger pressure is *very* slightly and gradually eased so that a little air can pass—without force—through the offending nostril. One or two attempts at this method will usually maintain stasis and also leave a free air passage. The tip of the nose can again be carefully rinsed.

E. TREMAIN BRADLEY, M.D., solo practice of general surgery, retired to Norfolk.

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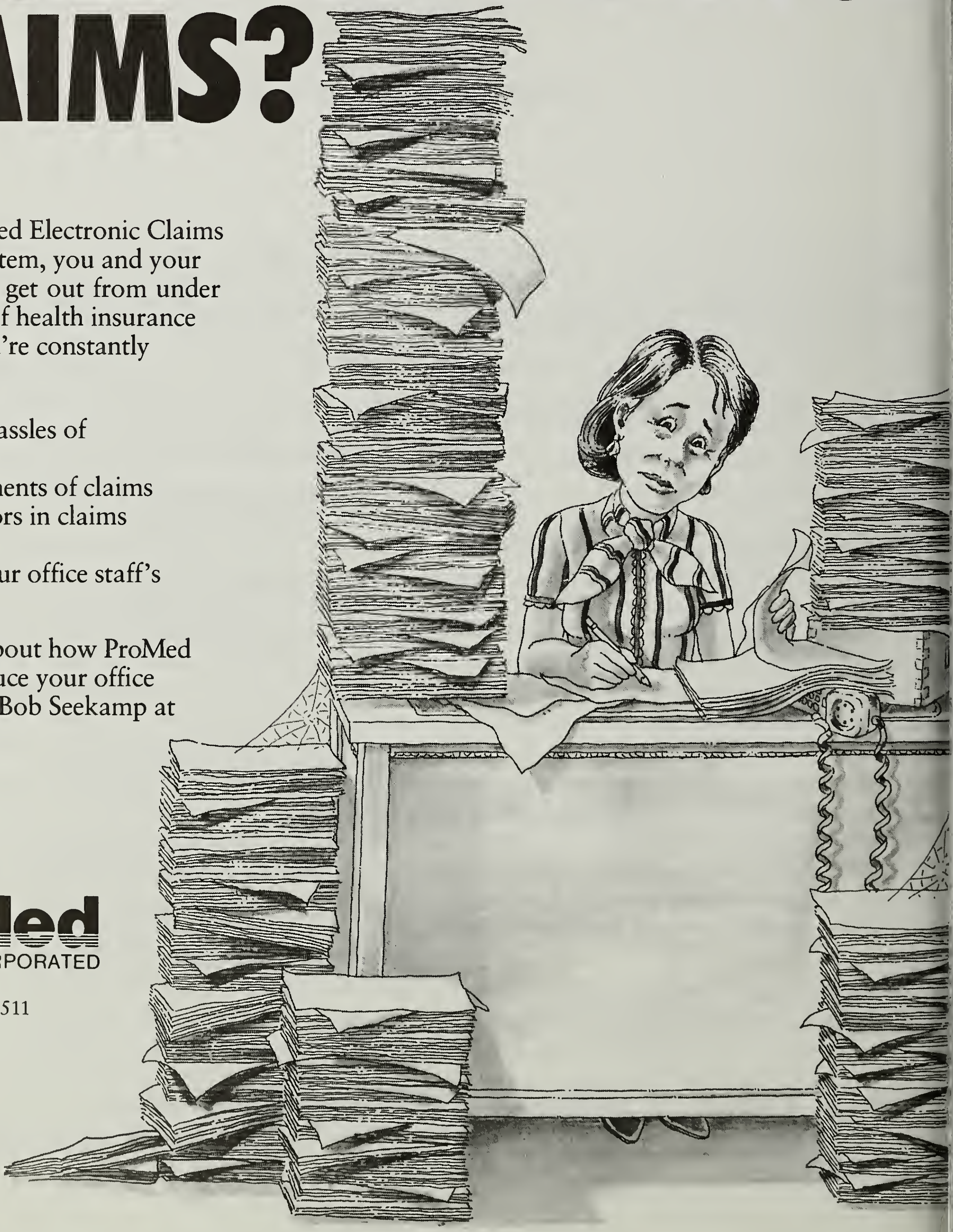

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Confidentiality and the Courts

ROBERT D. STEIN, M.D.

BACKGROUND: On Monday, 26 February 1990, WABC Television in New York City ran a story on its evening news telecast concerning a rape victim known as "The Central Park Jogger." During the course of that newscast and also on the following day, the network indicated that it had obtained the actual hospital records of that woman's hospitalization at Gaylord Hospital in Wallingford, Connecticut. It made no claims regarding how these records were obtained, nor did it confirm or deny that any of the woman's health care providers or their institutions had been the source of this information.

The news report, however, went on to describe certain aspects of the patient's care while quoting the record and highlighting various passages. Moreover, it went further and showed a copy of the actual inpatient record, including an entry on the patient's chart concerning HIV testing, and reported on the results of this test.

Gaylord Hospital has taken the position that these records were not provided to the media by the hospital itself, nor by any of its employees or designates. This is supported by a number of security measures which had been taken relative to this case in particular and to hospital policies in general. At present, the source from which these records were obtained is unknown, but it should be noted that copies of these records had been provided with the patient's written permission to the court system in New York to be used in the trial of several defendants accused of crimes relative to this case.

Subsequent to these events, the court had requested follow-up records concerning the patient. Since the hospital contends that the information was leaked after it was provided to the courts, it has refused to hand over these records unless and until it could be assured that their confidentiality could be guaranteed.

Confidentiality is one of the cornerstones upon which the relationship between patient and physician is based. Without it, patients might hesitate to reveal intimate but important information, or to submit tests which could lead to discrimination. Clinicians on the other hand might be reluctant to note sensitive information in charts, thereby having a negative effect on both the continuity and quality of care for patients. And what of the court system, insurance companies, HMOs and the news media, among others? What legal and ethical restraints are placed upon them?

As clinicians we must have a role in answering these important questions. Failure to do so places the delivery of clinical care for our patients at risk. It threatens the way we provide care and it will jeopardize our patients' health and well-being. And in the end, we are all patients.

Several days ago I ran into a colleague who is currently employed as a full-time hospital based physician. She had an interesting story to tell me about a patient with clinically significant findings whom she had just advised to have HIV testing. The patient asked some pertinent questions and then wanted to know if the results of the study would be confidential. My physician friend reassured the patient about the hospital's policy on confidentiality and pointed out that the patient's blood sample would be coded before being sent out to the reference lab in order to assure the patient's anonymity. The patient, however, was not convinced and wondered if someone other than his care-givers might see the chart and learn the results of the test. He wanted a 100%, iron-clad guarantee that the information would not intentionally or accidentally be released to others, thereby exposing him to discrimination. The physician sensed that there was something else on his mind, and when she asked, he responded quite readily.

It seems that he had in fact recently seen news broadcasts on television during which copies of the actual hospital medical records of a celebrated patient were paraded

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ROBERT D. STEIN, M.D., is an internist and chief of staff at the Gaylord Hospital in Wallingford, and is cochairman of the Connecticut Joint Practice Committee of the Connecticut State Medical Society and the Connecticut Nurses Association.

across the screen, presumably for the entire nation (or world when one considers satellite transmission) to see. Included in the purloined record was HIV testing information, the results of which were also reported to the public. "Fortunately," as he had heard the newsman say, "the results of the HIV test were negative." But what if they had not been? Would the story have run anyhow? And could not the psychosocial consequences have included loss of housing, job, health, life insurance, and other benefits, estrangement from spouse, family, friends, and colleagues? To make matters worse this celebrity patient had been brutally raped, was a victim and certainly "hadn't asked for it," and now was becoming a victim once again.

My friend's patient refused to be HIV tested.

Such is the dilemma we clinicians now face every day. We are given the charge to care for our patients, to ease their suffering, cure their diseases, and heal their wounds. We do this gladly but in order to do so we look, listen, smell, touch, test, and record before treating. And when we treat we do so cautiously, while observing the effects of our treatment, reserving the right to change course if the risks start to outweigh the benefits. *"Primum non nocere":* First, do no harm.

Examinations of our patients often lead to laboratory testing which in broad terms can be broken down into invasive and noninvasive tests. Noninvasive tests expose the patient to little or no risk, although the results may often be rewarding and quite helpful. Invasive tests on the other hand, do "invade" the sanctity of the body to a greater or lesser degree and do have an implied greater risk than noninvasive tests. The yield from such studies, however, may often be great and therefore assist in establishing an important diagnosis, thereby allowing treatment to proceed. When one considers doing an invasive study one must weigh the risks of the study against the possible benefits that the study may have in revealing a particular diagnosis. If the risk far outweighs the benefits, the study will often not be done.

Although acts of commission can have risks so, too, may acts of omission. Giving penicillin to a patient allergic to this medication may certainly have disastrous consequences, as might lack of antibiotic therapy for an elderly patient fearful of going to the doctor, or lack of prenatal care for an indigent mother with a history of drug abuse and a fear of HIV testing.

It is therefore important to recognize that all our actions committed or omitted, will influence our patients' well being, and always must be considered on the risk-benefit scale. If a course of action is seen as having much greater benefit than risk, we would tend to choose that course. In situations where the reverse is true, however, the balance would be tipped in the opposite direction and the action avoided.

But not all such decisions are made by us as care-givers. Patients should and often are included in the dialogue and participate in the decision-making process. They give informed consent, seek second opinions, refuse seemingly noxious treatments, and ultimately may change physicians or other health care providers if there is significant disagreement. On occasion they attempt to direct their own care, and if we as clinicians determine that their chosen course will be significantly deleterious to their health, it is our ethical obligation to state our concerns and refuse to participate in this activity. The patient of course has the right to seek this care elsewhere.

Clinical competency, accessibility, trust, and confidentiality are the cornerstones upon which is founded the patient-physician (clinician) relationship. Without these, proper clinical care, and therefore our patients' health, cannot be assured. Although traditionally these issues used to be more clear cut, we now find that the waters have been muddied by legislative, economic, technical, and judicial factors. The AIDS crisis has been further inflamed by societal hysteria which, in some cases, has been heightened by misdirected and politically motivated government intervention. Rising health costs have enabled government and the insurance industry to justify restrictive access to care by refusing financial support in some instances, and the courts have sought medical records in increasing numbers in order to support or refute charges and to render decisions. Patients and clinicians have been lured to HMOs and other "managed care" plans because of a variety of financial considerations. Computers have proliferated to the point that health records are requested routinely in order to support health-care claims and are apparently then transmitted to a number of end points in a computer network thereby establishing what amounts to a *de facto* national data base.

Although clinicians are strongly bound by law and by ethics to patient confidentiality, lesser legal restraints have been placed on primary insurance carriers, and none on those other carriers at a distance who have no direct contact with the patient. Hospital medical records typically are stamped with the words "Confidential Medical Records—Not to be Reproduced Without Written Permission of the Patient." This, however, is a fantasy, since in reality insurance companies routinely require patients to sign a release to obtain such information if the patient in fact wants his or her medical services to be paid for. The patient certainly has the right to refuse to sign this, but in so doing he or she also assumes responsibility for paying the bills. Once signed the release allows the insurance carrier to obtain and review "any and all clinical records" and to provide such information to other insurance carriers that request it, thereby exposing those records to the purview of individuals from the East Coast to the West Coast.

Once they are entered into this "National Data Bank," who is responsible for the patient's record? Who guarantees its confidentiality and security then? Who can assure that it cannot be altered electronically either intentionally or not? What sanctions are taken against those who share this information with inappropriate entities, such as banks, housing authorities, government agencies, employers, news media, etc.? And how can it be determined where the information was leaked from, whether it be lawyer, insurance company, computer technician, or other individual or institution for a variety of motives? The point here is that the confidentiality of the medical record has become an anachronism, but without it a proper patient-physician (clinician) relationship cannot exist, and without it appropriate care cannot be given.

To the public an issue such as this may seem of little importance. They may be apathetic with a sense that most of the time the information provided would not be so sensitive after all, and therefore a small price to pay for the privilege of having one's health care paid for. That notion would probably be further supported by the view that doctors and hospitals are making "too much money" and "have something to hide" in these records. Certainly the loss of security of the medical record as stated above does influence the cautious way that these records are now completed. However, does this benefit the patient's actual care?

If a patient walks into a doctor's office for care of a potentially serious condition, the patient must be able to answer important and often sensitive, incriminating questions honestly and with confidentiality. Patients must allow a physical examination and laboratory testing when appropriate and they must pursue treatment if indicated. Patients will hesitate to cooperate if they sense that their responses to questions, their laboratory test results or other sensitive information will appear on nationally televised news programs, or if they fear losing life insurance, job, or family as a direct result of such disclosure. Therefore appropriate medical care cannot be provided, and our patients will be placed at great risk, surely even greater than we as clinicians or record keepers will be.

Sooner or later, of course, we are all patients, and it follows that without confidentiality, the delivery of quality health care as we now know and expect it, will cease.

Editorial

The Central Park Jogger and Confidentiality

At a recent CSMS Council meeting, Dr. Roger Beck reported that he had attended a meeting of the CSMS Joint Practice Committee the previous evening, and the subject of confidentiality of records was the main item on the agenda. A videotape of news broadcasts from New York Channels 2 and 7 entitled "The Central Park Jogger" were shown, displaying a flagrant breach of patient confidentiality and privacy by exposing actual patient records on the screen.

Following considerable discussion, it was voted that CSMS draw up a position on the issue of confidentiality, citing this particular case as an example, and that this be addressed in letters to the stations, and to the administrator of Gaylord Hospital indicating the Society's support for his position. It was further voted that the position paper also be published in *Connecticut Medicine,* the CSMS Journal, for the information of the membership.

As the person who first raised the issue, Dr. Robert Stein of Wallingford was asked to prepare the paper, which is published in this issue of *Connecticut Medicine* as a special article entitled "Confidentiality and the Courts." As he explains, this particularly outrageous violation of a rape victim's medical privacy by the news media and perhaps even by court officials is only the tip of an iceberg of routine transmission of private medical records to a host of strangers, some of whom could use the information to deny health or life insurance coverage for a patient, or even employment or housing, and for any number of ulterior reasons.

If any semblance of patient privacy is to be preserved in this age of instant access, and if any confidential significance is to remain inherent in the patient-physician relationship so necessary to the integrity and effectiveness of medical care, then third-party payers, court officials, and media journalists must somehow be made responsible for observing the same ethical standards of medical confidentiality as have been traditional for physicians, nurses, other health care professionals, and hospitals. **No patient deserves less.**

Mehdi Eslami, M.D.
CSMS President

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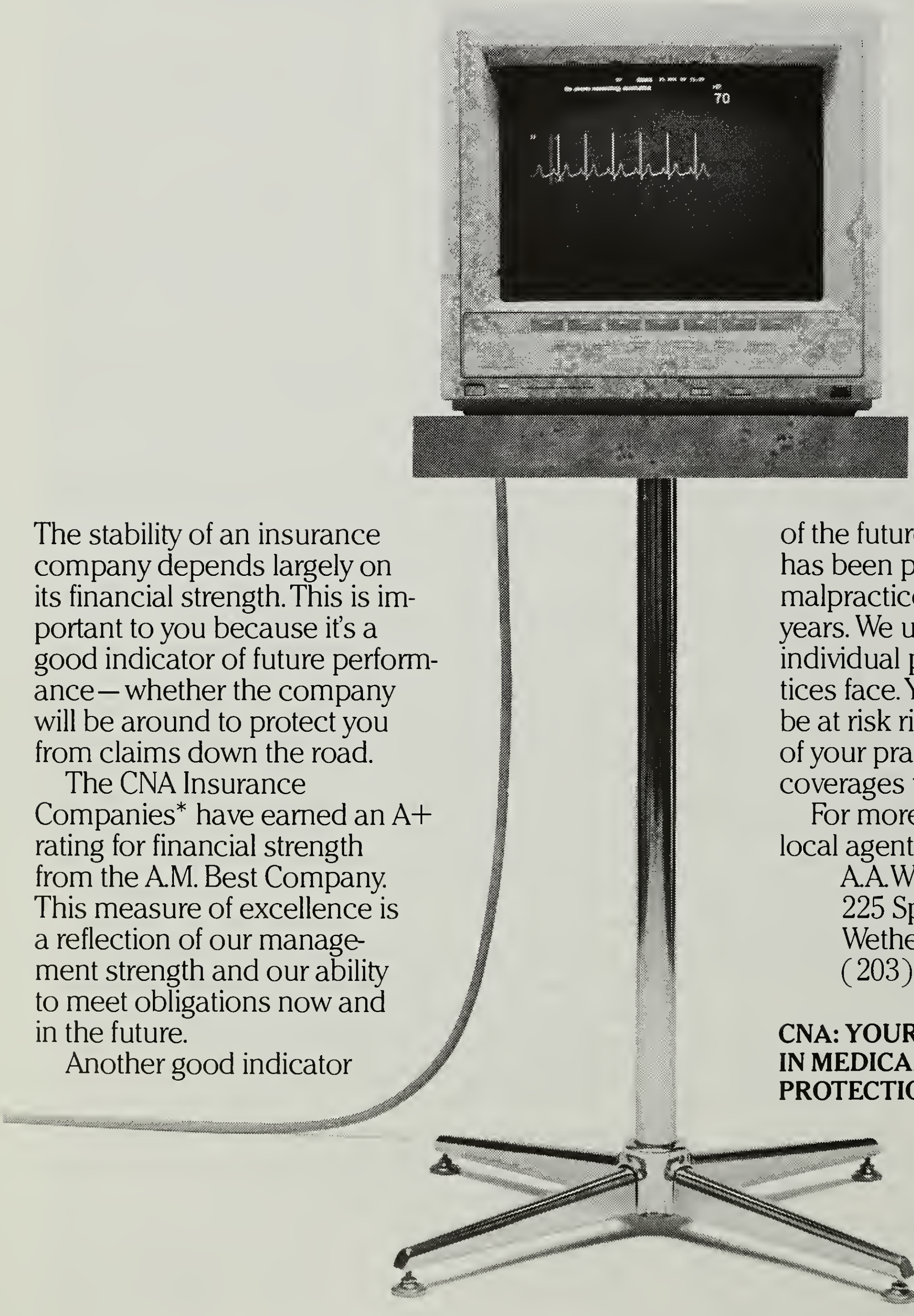

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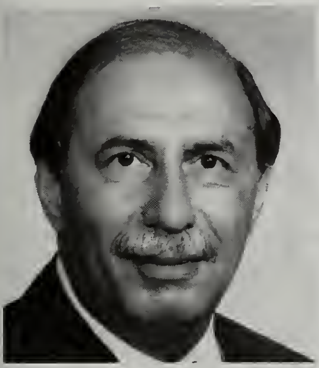

You perhaps have seen media coverage of the AMA House of Delegates meeting held in Chicago June 24 to 28. Elsewhere in *Connecticut Medicine* you will see a summary of actions taken at that convention on behalf of our profession. Some may or may not agree in every detail with the outcome, but few who were there would deny that the procedures followed were truly impressive. This remarkable AMA democratic process deserves our special attention.

The sheer volume of reports and issues addressed this year was unprecedented. The looseleaf "Delegates' Handbook" was thicker than the New York telephone book. Every resolution in it had its origin during the months preceding in some local physicians' concerns expressed to their county, state, or specialty society colleagues and supported by them for wider consideration.

Each of these items was assigned to one of ten reference committees, each committee taking testimony and hearing debate not only from delegates, but also from rank-and-file AMA members. The reports of each of these reference committees were then considered by the full House in plenary session, often with further debate and discussion growing out of the daily 6:30 A.M. meetings of regional groupings, such as our New England Delegation. There, local delegates assigned to attend and/or testify at the various hearings would review the recommendations of each reference committee. These regional caucuses also interviewed each of the candidates running for AMA office. The House rejected some resolutions, referred some to appropriate AMA Councils or to the Trustees, and accepted some via the "consent calendar." Other issues were debated at length on the floor before a definitive vote was taken, sometimes with controversial results.

Besides voting on issues, the House also elected (and defeated) dozens of physician-candidates for AMA office, Board seats, and the various councils. As among the issues at stake, these outcomes were not always predictable, with a few incumbents ousted as well as newcomers elected. Dr. Bob McAfee of Portland, Maine, was reelected as an AMA Trustee, assuring a continuing voice for New England in the highest echelons of organized medicine.

The AMA may well be our nation's most democratic voluntary organization. This AMA democracy guards you against the entrenchment of unrepresentative leadership, and provides a vehicle by which the best ideas of individual members can, by common agreement, quickly become effective in the national forum. Those members whose sole organizational activity lies in the timely payment of their AMA dues also contribute equally to the great power that the AMA can bring to bear in carrying out the consensus growing out of the meeting. May their numbers continue to increase everywhere, as they have here in Connecticut for each of the past eight years!

Consistently, this national medical consensus has involved AMA in the vigorous defense of your ability to practice medicine in accordance with your best medical judgement and in your patient's best interest, using informed standards imposed by the medical profession upon itself, not dictated by third parties whose primary interest in the patient is political or economic rather than medical. At times, the AMA's is the *only* voice raised in federal bureaus and congressional hearings to defend the integrity of your sound medical judgment and to preserve inviolate the physician-patient relationship so essential to effective care. In this national arena, physicians, through their AMA dues, are sometimes the only real patient advocates left.

Experiencing AMA democracy in action like this has convinced me that our profession and our patients need the support of *every* doctor at *every* level of organization: county, state, and AMA. With ever greater challenges looming, it will take the *whole* federation of physicians, working together in convention and between conventions, to keep American medicine healthy in the 90's!

Mehdi S. Eslami, M.D.
President

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The Class of 1994

ROBERT U. MASSEY, M.D.

This month members of the medical school class of 1994, almost 16,000 of them, begin their careers in the nation's 126 medical schools. The decline in applications of the past few years has apparently stopped; in fact, many schools have reported an increase. At the University of Connecticut in-state applications are up 15% over last year, and out-of-state applications are 20% higher. Nationally this year's applicant total, just under 29 thousand, was 9% higher than in 1989; the low point had been reached about four years ago. The major factor determining applicant totals is the number of 22- and 23-year-olds in the population, but many of us were fearful that medicine had lost its appeal. Medicine's prestige was declining, doctors were telling their children and their friends' children not to consider medicine; making lots of money in a hurry, we were told, had become the chief concern of students in the 1980s.

Much of this may have been good for medicine. When it was suspected that the doctor shortage of the 1960s might turn into the doctor glut of the 1990s, applicant numbers began to fall. If most of those who turned to other careers were the ones looking for early riches or social power and prestige, their loss to medicine was no loss at all, but rather a gain, especially for those of us who might have had to live with them as colleagues or consult them as patients.

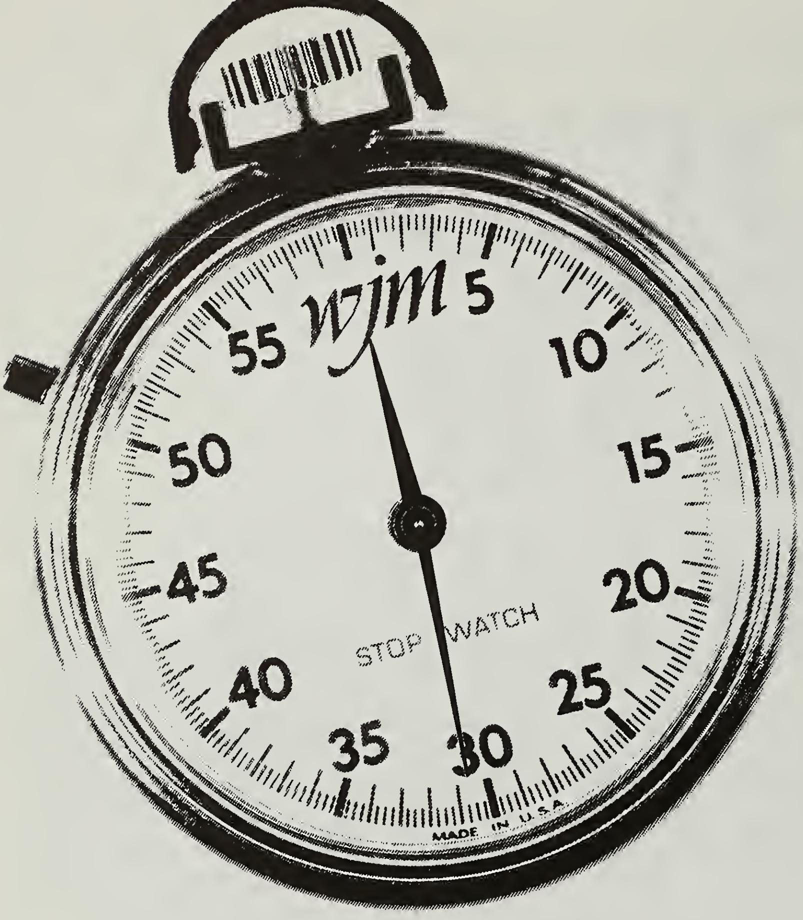
The class of 1994 at the University of Connecticut will be almost half (45%) women, as it has been for some years now. After the turn of the century the distinctive differences that women will by then have brought to our profession will be evident. They are not yet represented as well in organized medicine and on medical school faculties as they are in medical school classes and on the house staffs of teaching hospitals, but they will be, and historians of 2050 will have a heyday describing and explaining the distinctiveness that was becoming apparent in medical practice in the first decades of the new century.

By the year 2040 those entering medical school this month will be in their early 70s, retiring and reflecting on the old days. Their colleagues will look upon them as an antique crowd, holdovers from the old century, the century in which Victoria died and Russia still had a czar and Germany and Austria-Hungary had kaisers, the century that still knew Koch and Osler, Stevenson and Tolstoy; the century of the great wars, the rebirth of Europe, and the rising economic power of the Pacific nations; a century that some thought we would never get out of alive.

As we look ahead to their 50 years of work in medicine we can imagine only a quickening pace of change, remarking, as we often do to our younger colleagues, that medicine has never changed so much as it has in the last 25 years. If indeed the rate of change, driven essentially by technology and population growth, is exponential, then it must reach a rate that is humanly unsustainable. Like other biological phenomena, change in human societies must describe a kind of sigmoid curve, increasing slowly over most of the history of mankind and throughout the millenia of prehistory, beginning a distinctly steeper ascent in our corner of the world in the eighteenth century, and now seeming to many of us about as vertical as it can get. Surely it must soon begin the flatter, gentler part of its ascent. The long delay between the 1969 moon landing and the anticipated Mars landing (2030?) suggests that for man-in-space technology the pace has already slowed. Is this about to happen in our other technologies as well? Members of the medical school class of '94 will know by the time they are in mid-career, say in 2010, whether the growth of biomedical science and technology has begun to slacken, either because nature has refused to yield up some of her most closely held secrets, or because, having run out of money and interest, we have turned to other things.

No matter. If these fin-de-siecle students keep their hearts and minds open to the work of their profession and the meaning of their vocation in medicine, they, like Thomas Browne, 350 years before them, will practice their art in tranquility though scientific, political, and social change should continue to roar about them as furiously as it whirled about the physician of Norwich in his untranquil 17th century.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.



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Connecticut's New Abortion Statute

JOSEPH M. HEALEY

ONE highlight of the past session of the Connecticut legislature was the passage of an abortion statute which brought Connecticut law into conformity with existing federal guidelines and which clarified the rights of minors in Connecticut with respect to abortion. Last month's column introduced the new statute.[1] This month's column will look at the provisions dealing with minors.

In addition to the considerable controversy surrounding the general legal availability of abortion in the United States, there has been additional controversy surrounding the extent to which minor women should have the same access to abortion as adult women. Much of this discussion has centered on the role of the minor's parent(s) or guardian(s). Proponents of the minor's right of access tend to view the issue as one involving the right of the minor to make very personal decisions on her own and for herself. Opponents question the validity of decisions made by those whose maturity may be in dispute, under less than ideal situations, without the support or assistance of their families. What has emerged in the Connecticut statute is a compromise which recognizes a minor's access to abortion while imposing information, counseling and documentation requirements. While not a perfect solution, the overall effect of the requirements is to affirm the minor's right to informed choice about abortion.

For the purpose of the statute, a minor is a person under the age of sixteen. Before an abortion may be performed on a minor, the physician or counselor is required to satisfy six requirements with respect to pregnancy information and counseling: (1) an explanation that the information is being given "objectively" and is not intended to coerce or persuade the minor to choose one of the options; (2) an explanation of the minor's right to withdraw or reconsider her decision anytime before the abortion is performed or during the time period when abortion is legally permitted; (3) an explanation of the alternative choices involving either carrying the pregnancy or terminating the pregnancy, including a discussion of the public and private agencies available to offer assistance in carrying out the decision; (4) a discussion of the availability of birth control information from public and private agencies; (5) a discussion of the possibility of involving the minor's parent(s), guardian(s), or other adult family members in the decision; and (6) the provision of adequate opportunity for the minor to ask questions and to obtain useful information.

After the information and counseling process has been completed, the physician or counselor is required to have the minor sign a consent form which documents that the required information and process have been provided. The information which must be included in the form resembles closely that contained in the six categories listed above, with one addition. If applicable, it shall be documented that the minor has determined that not involving parent(s), guardian(s), or other adult family members is in the minor's best interest. However, the provisions of the statute shall not apply when a medical emergency exists and the health, safety, or well-being of the minor requires an immediate abortion.

The battle over the right of parents or guardians to participate in their minor child's abortion decision is not entirely over. Some proponents of the Connecticut legislation view this legislation as the first step toward reconsidering the entire issue. During the same week that it decided the Cruzan case (to be discussed in a forthcoming column), the United States Supreme Court decided two cases from other states dealing with minors' rights in the abortion context which might influence further Connecticut developments. These will be the subject of my next column.

REFERENCE

1. "An Act Concerning the Repeal of Certain Statutes" (Connecticut Public Act No. 90-113).

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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50 Years Ago

From the *Journal of the Connecticut State Medical Society* August 1940

THE CUSHING MEMORIAL LIBRARY AT YALE

The left wing of the new medical library now under construction at the Yale School of Medicine will be known as the Cushing Library in honor of the late Harvey Cushing. To the great collection on historical medicine left by Dr. Cushing will be added the collections of Professor John F. Fulton of Yale and of Dr. Arnold Klebs of Switzerland. The Cushing Library, in the opinion of Yale authorities, will represent one of the most important collections dealing with the history of medicine and medical sciences in the world. This portion of the building will house about four hundred thousand books and is expected to be ready for occupancy in September, 1940. The right wing, or general medical library, is to be administered by the Committee on the Library of the School of Medicine under the chairmanship of Professor George H. Smith. On the second floor of the new building will be located the offices of the administration for the School of Medicine, and on this floor also it is planned to locate the Beaumont Memorial Room, which will house the Beaumont collection of medical memorabilia and in which meetings may be held.

TESTIMONIAL DINNER FOR DOCTOR GEORGE BLUMER

About 300 persons attended a testimonial dinner at the Hotel Taft, New Haven, June 17, 1940, given in honor of Doctor George Blumer on the occasion of his retirement from active service in the School of Medicine, Yale University.

Former students, his associates and colleagues gathered to show their respect and affection for George Blumer, who for 34 years has faithfully served the University, the community and the state.

In the University he was successively Professor of Theory and Practice of Medicine, John Slade Ely Professor of Theory and Practice of Medicine, David P. Smith Clinical Professor of Medicine, and from 1910-1920 Dean of the School.

Doctor Blumer was President of the Connecticut State Medical Society for the year 1920-1921 and since 1932 has been a delegate to the American Medical Association.

Doctor Francis G. Blake was toastmaster on this occasion. Talks extolling Doctor Blumer's capabilities and telling of his pleasant shortcomings were given Dean Stanhope Bayne-Jones, president-emeritus of the University, Doctor James R. Angell, Doctor Milton C. Winternitz, Doctor William F. Verdi, and Doctor Fu-chun Yen, a graduate of the School, a former student of Doctor Blumer's, and Minister of Health of the Republic of China.

Doctor S. J. Goldberg, on behalf of his friends, presented Doctor Blumer with a suitable gift. Doctor Blumer responded in his usual interesting manner and expressed his deep gratitude for the testimonial.

WINCHESTER HOSPITAL IN WEST HAVEN TO CLOSE

According to the daily press the Board of Directors of the New Haven Hospital has decided to close the William Wirt Winchester Hospital in West Haven and to transfer the tuberculosis service from there to the New Haven Hospital. The Winchester Hospital has been operated at a loss since its opening under the management of the New Haven Hospital in 1927. There appears to be little need any more for an institution of this type. Connecticut now has a ratio of approximately three sanitoria beds per annual death from tuberculosis, one of the highest ratios of any state and twice as high as that of the country as a whole.

The history of the Winchester Hospital is an interesting one. Established for the care of tuberculosis patients in 1916, through the gifts for Mrs. Sarah L. Winchester, it was leased to the Federal government in March, 1918, and established as U.S. Army Hospital No. 16 for tuberculosis soldiers. After the armistice it was transferred to the Public Health Service and later to the Veteran's Bureau, finally reverting to the New Haven Hospital nine years after its completion.

From the Executive Director's Office

COUNCIL MINUTES

Wednesday, 25 July 1990

Attendance

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Ahamed, Beck, Brooks, Cottle, Dardick, Eslami, Fox, Franklin, Freedman, Meridy, Orphanos, Petrie, Petro, Redmond, Sadowski, Wetstone, Wolfson, Zanker, and Zeppieri.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Garofalo, Ms. Ballou, Mrs. Connelly, Mr. Tomat (FCMA), Mr. Coffey (HCMA), and Mr. Freberg (NHCMA).

Absent were: Drs. Blum, Bobruff, Chmieleski, Deren, Hollister, Intravia, Kamens, Keating, Lesnik, McDonnell, Parikh, Reyelt, Jr., Robbins, Sosa, Van Nostrand, and Welch.

Report of the President

Dr. Eslami reported on his attendance at the AMA Annual Meeting and stated that he was impressed as to how hard the Connecticut delegation worked; they put in long hours usually from 6:30 A.M. to 4:30 P.M. He stated that John C. Tupper, M.D. of Davis, California, was inaugurated as President and John J. Ring, M.D. of Mudelein, Illinois, was elected President-Elect. Robert E. McAfee, M.D., a member of the New England delegation, was reelected to the Board of Trustees and also elected by the Board as its Vice-Chairman.

It was reported that since the last Council meeting, he and other CSMS representatives attended a meeting with representatives of the Insurance Association of Connecticut. Some of the subjects discussed were utilization review, shortage of neonatal beds, managed care, etc. It was reported that although there was not agreement on all the issues discussed, the dialogue should be kept going and future meetings will be held.

Dr. Eslami also reported on a meeting held with representatives of AARP at the CSMS building and stated that members of the AARP asked what they could do to help reduce the cost of health care. Some of the issues discussed were professional liability costs, tort reform, long-term health care, and the pamphlet entitled "Death with Dignity." AARP representatives expressed concern that the state had provided 40 million dollars for the COMPACE program and that 32 million has already been expended in six months. The groups will continue to meet and will make every effort to assist each other in programs of mutual interest.

Report of the Executive Director

Mr. Norbeck reported that Dr. Arnold Relman will retire next June as Editor-in-Chief of the *New England Journal of Medicine*.

He reported that Dr. Kamens ran a strong campaign in Chicago for a seat on the Council on Medical Service, however, it was almost impossible to overcome the anti-PRO sentiment in the large states. There was a great deal of comment from members of the House concerning his fine campaign and that we should be proud of him.

It was noted that Pennsylvania joined Massachusetts and Rhode Island last month when their legislature approved across-the-board mandatory assignment. It is not tied to licensure, but provides for fines up to $5,000 if violated. The bill takes effect 60 days following the governor's signature.

He further reported that in New York, the legislature capped physicians' fees at 115% of the Medicare reimbursement rate for 1991 and 1992, and 110% for 1993. A federal law, which takes effect 1 January 1991 limits the amount physicians can charge to 125% of Medicare reimbursement rate in 1991, 120% for 1992, and 115% for 1993. New York physicians were very angry about this action, having waged a very expensive campaign against it.

Report of the AMA Delegation

A summary of the 1990 Annual Meeting of the AMA House of Delegates had been distributed to all members of the Council with the agenda and Stewart Petrie, M.D., and other members of the delegation highlighted some of the issues presented at the meeting which were:

(1) The AMA Board of Trustees provided the House of Delegates with the recommendations and conclusions of the investigation of the recent financial transactions involving various officers of the AMA and assured the House that financial restitution had been made in all

instances and that safeguard regulations had been adopted that would monitor all future financial transactions.

(2) The House adopted a report from the Council on Ethical and Judicial Affairs that describes six areas of the fundamental rights of patients in their relationship with physicians. Following are some excerpts from the complete text of the report:

(a) Right to receive information from physicians and to discuss the benefits, risks and cost of appropriate treatment alternatives. . . .

(b) Right to make decisions regarding the health care that is recommended by his or her physician. . . .

(c) Right to courtesy, respect, dignity, responsiveness, and timely attention to their needs. . . .

(d) Right to confidentiality. . . .

(e) Right to continuity of health care. The physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient. . .and may not discontinue treatment of a patient as long as further treatment is medically indicated. . . .

(f) Right to have available adequate health care. . . . Fulfillment of this right is dependent on society providing resources so that no patient is deprived of necessary care because of inability to pay for that care. Physicians should continue their traditional assumption of a part of the responsibility for the medical care of those who cannot afford essential health care.

(3) The Board of Trustees presented a basic package of benefits for the required employer insurance program which included:

(a) Enactment of any program requiring employer coverage should not create insurmountable financial obligations on small employers.

(b) Most employer-provider health insurance will continue in the future to exceed substantially the minimum benefits that they are recommending.

(c) The goal of the Association is to extend affordable coverage where none now exists.

(d) The medical profession must be involved in the final process of determining benefits.

In a related action, the House approved the following resolution that asked the AMA to:

RESOLVED, That the AMA give high priority and commit all appropriate resources to provide leadership and ensure that this nation begins the process of defining in detail the basic nationwide standards for a uniform, minimum yet adequate health care benefits package for the unemployed uninsured.

(4) The House considered four resolutions regarding the new Medicare RBRVS physician-payment system that addressed issues of geographic disparity and other economic considerations and adopted a resolution that calls on the AMA to give continued highest priority in overseeing the implementation of this payment schedule.

(5) The House filed an information report describing the status of "Health Access America," which integrates AMA policies into one cohesive approach to build on the strengths of the U.S. health care system and address its significant weaknesses. The report outlined:

(a) Several categories of medical care expenditures over which physicians have little or no control.

(b) Itemized additional issues which contribute to medical care expenditures, eg, increased aging of the American population, new medical technologies, federal/state regulations, poverty, alcohol and drug abuse, and violence.

(c) AMA efforts to educate the public.

(6) The delegates approved a policy that called upon the AMA to:

(a) Communicate its strong support of the appropriate and humane use of animals in research and commend HHS Secretary Sullivan for his public support of such research that benefits the health and well-being of human beings and animals.

(b) Encourage its members to make every effort to inform their patients, community groups, legislators, and media that, while the use of non-animal models in research is desirable when possible, the continued use of animals is critical for the development of new and more effective medical treatments of disease for both human beings and animals.

(c) Provide reasonable and appropriate assistance to researchers whose projects have have been hampered by animal activist groups.

(d) To establish a repository of information concerning such research delays and provide an evaluation of the impact of these delays to the AMA members and the public.

(7) The House approved policy regarding the National Practitioner Data Bank asking the AMA to:

(a) Request that the Department of Health and Human Services instruct the National Practitioner Data Bank to institute physician notification of adverse data-bank entries with verification of receipt by the physician.

(b) Notify its members of the AMA resources to assist individual physicians having difficulties with the National Practitioner Data Bank.

Other members of the delegation discussed the following issues:

(a) AMA personnel policies.

(b) AM News autonomy.

(c) Physicians' profiles.

(d) Make-up of the Board of Trustees.

(e) The publication of names of physicians running for national office.

(f) Medicare regulations.

Dr. Petrie commended the delegation for their diligent efforts at the meeting.

Ad Hoc Committee—Workers' Compensation Commission

Dr. Zeppieri distributed the program for the Third Disabled Workers' Symposium which is based on the return of the disabled worker to the workplace. The meeting will be held on 17-18 October 1990 at the Park Plaza Hotel, New Haven. He further reported on another meeting held with Workers' Compensation Commissioners concerning the promulgation of a restricted list of physicians to treat compensation cases. He reported that for the present this list has been put on hold, however, there is a lot of pressure by the insurers, employers and CBIA to proceed with a restricted list. A course has been outlined that will be presented in January concerning this issue which it is anticipated will be presented to hospitals throughout the state.

He reported that by his participation in the International Association of Industrial Accident Boards and Commissions, he was able to rebut a letter that had been sent to the International Association. . .recommending that they go on record for legislatures around the country to try to promote the formation of restricted lists of physicians approved for treating workers compensation injuries.

He further reported that the Ad Hoc Committee, at the invitation of CBIA, had several meetings with representatives of that organization to discuss items of mutual interest, one item that both organizations thought might be useful was the development of a uniform reporting form for physicians providing care for industrial injuries and this proposal is being pursued.

Report of AMA Hospital Medical Staff Section Meeting

Howard W. Meridy, M.D., had submitted a written report on the 15th Assembly of the Hospital Medical Staff Section of The AMA, which met in Chicago, 21-25 June 1990. Three of the major issues discussed at the meeting were: "The National Practitioner Data Bank," "Legal Issues involved in Economic Credentialing," and "Building Effective Hospital-Physician Relationships." Three reference committees heard testimony on approximately 68 resolutions, 11 of which went on to the AMA House of Delegates. For the most part, the issues discussed at the Hospital Medical Staff Section meeting paralleled those debated in the House of Delegates.

Membership Development

Jerome Freedman, M.D., Chairman of the Ad Hoc Committee on Membership, reported that a meeting of the Executive Directors and their staffs of the Fairfield, Hartford, and New Haven Counties held a meeting at the CSMS office on 17 July for the purpose of discussing various areas of membership, ie, discouraging split membership between county and state, increasing membership, reasons for loss of membership and reporting methods between county and state. It is anticipated that within three months, many of the problems discussed could be eliminated.

Life Members:

It was VOTED to receive, as information, the names of the following physicians who have been granted Life Membership effective 1 January 1990:

William H. Tripp, M.D., West Hartford (H)

Desmond B. DeVille, M.D., Middletown (M)

Liaison Committee with Connecticut Bar Association

At the request of the Fairfield County Medical Association Board of Trustees, the following members were appointed to the Liaison Committee with the Connecticut Bar Association: Robert S. Walzer, M.D., J.D., Norwalk and Alan D. Lieberson, M.D., J.D., Westport.

Dates for Future Council Meetings

Thursday, 6 September 1990

Wednesday, 17 October 1990

N.B. The foregoing is a summary of the proceedings and actions of the Council on July 25, 1990. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested members of the Society.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a free service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

AMBULATORY CARE

Physician needed full-time for an ambulatory care center in the Greater Bridgeport Area. Broad general medical, orthopedic, and minor surgery skills required. F.P., E.M., and general IM preferred. Salary and benefits commensurate with experience. Please send CV to Dominick V. Sorge, M.D., 4490 Main St., Bridgeport, CT 06606.

EMERGENCY MEDICINE

Middlesex Memorial Hospital, a 240-bed community hospital with a Residency Program in Family Practice, is recruiting a full-time medical director, and one full-time staff physician, to staff our second free-standing emergency facility owned and operated by the Hospital as a division of Middlesex Memorial's Department of Emergency Service. The facility has been approved by the State's Commission on Hospitals and Health Care to operate 12 hours a day, seven days a week, and will receive ambulances and be an integral part of the community's EMS system. It is located in a highly desirable and rapidly growing residential community approximately 20 miles from Hartford and Middletown. Physicians will be credentialled as members of the Emergency Department at Middlesex, and will have the opportunity to work extra shifts in the Emergency Department if desired. We would prefer physicians with emergency department experience and board certification or eligibility in EM, IM, or FP. The medical director will have on-site responsibility for policy development and implementation, staff, QA, etc. Highly competitive salary, plus incentive. A complete range of outstanding hospital benefits. CV's to W. Gordon Van Nes, M.D., FACEP, Chairman, Department of Emergency Services, Middlesex Memorial Hospital, Middletown, CT 06457. Telephone: 344-6691.

INTERNAL MEDICINE

BC/BE Internist for private practice with coverage and guaranteed income sponsored by expanding full service hospital three hours from NYC and Boston in attractive four season community. Send CV to: Yvonne Nakashian, 115 Spencer St., Winsted, CT 06098.

Internist/Primary Care—Excellent and unusual opportunity for BC/BE Internist or FP to attain early partnership in very busy Hartford area. Solo, private practice, associated with Hartford Hospital. Practice consists of suburban and urban offices. Very enjoyable patient load. No welfare or nursing home patients. No financial investment. P.O. Box 14344, Hartford, CT 06114.

Locum Tenens wanted for active internal medicine practice in beautiful Northwestern Connecticut. Three to 12 months assignment beginning 1990-91. Salary plus assistance in living accommodations. Write: P.O. Box 1168, Sharon, CT 06069.

Pulmonary Medicine. Board Certified/Board Eligible pulmonary internist sought for pulmonary/critical care practice in the Hartford, CT area. Seeking associate leading to early partnership for office based practice, with active involvement in community hospital intensive care units, respiratory therapy departments and PFT labs. At present practice is entirely oriented to pulmonary disease/critical care; there is ample opportunity to remain skilled in all pulmonary.critical care procedures. Practitioners interested in a traditional private practice in an attractive area of New England, will be most attracted to this position. Position available at present; will consider candidates available for July 1991. Send CV and reply to: Northeastern Pulmonary Associates, 43 Main St., Rockville, CT 06066.

OBSTETRICS & GYNECOLOGY

Southwest Connecticut. Excellent opportunity for female/male, BC/BE, Ob/Gyns. Well established progressive practice needs a new partner to replace retiring physician. We do in-office ultrasounds, colposcopy and fetal monitoring. Located across from hospital. Send CV to: Tim Sharpe, M.D., 284 Broad St., Milford, CT 06460.

PART-TIME

Part-time (15 hours/week) physician sought for Student Health Services at Southern Connecticut State University in New Haven. Willing to do some gyn work (not surgery) desired but not essential. Hours: 2:00 P.M.-5:00 P.M., Monday through Friday. Reply to (203) 397-4457.

M.D. Health Plan seeks a physician to serve as part-time Assistant Medical Director. The qualified candidate should be an active practicing physician with two years experience in application of quality assurance and utilization management techniques in a managed care environment preferably HMO. Exceptional written and communication skills are a must. Salary is negotiable. Interested candidates should send a resume to: D.A. Hayward, President & CEO; M.D. Health Plan, 6 Devine St., North Haven, CT 06473.

The Connecticut State Department of Education's Division of Rehabilitation Services is currently recruiting for contractual part-time Medical Consultants as follows: District Medical Consultants ($45.00/hr) and District Psychiatric Consultants ($45.00/hr). For further information, interested candidates should contact and/or submit a letter of application, vitae and copy of license to: Albert J. Sidlovsky, Jr., Consultant, Medical Relations, Division of Rehabilitation Services, Bureau of Organizational Support, 10 Griffin Road North, Windsor, CT 06095. Tel: (203) 298-2036.

PEDIATRICS

Exceptional opportunity to join a pediatric group practice of four BC/BE pediatricians. Practice is located in shoreline community five miles from Yale-New Haven Medical Center, our chief hospital affiliation. Sole owner is original partner of practice established in 1955. Starting salary $80,000.00 per year with buy-in option after one year. Part time position also available. Call (203)248-4846 any evening after 8:00 P.M.

BC/BE Pediatrician wanted for very active practice in Central Connecticut, leading to partnership with purchase of practice. Medical school and excellent hospitals available. Two hours to New York City, Boston or Vermont skiing. Call (203)242-8827 or (203)242-7071 after 6:00 P.M. or write: Levine M.D./Werner, M.D., 34 Jerome Ave., Bloomfield, CT 06002.

PRIMARY CARE

Occupational Health. Active occupational health center has a half-time position immediately available for a physician who is BE/BC in primary care medicine. Hours are Monday through Friday, 1:00 P.M. to 5:00 P.M., at two different sites. Very likely to be full time in future. Please contact: Allen M. Ford, M.D., 140 Grandview Ave., Waterbury, CT 06708. (203) 573-8114.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

FAMILY PRACTICE

Dec. '90. Age 32. Presently in practice. Nat'l bds. AB cert. M.D., University of Pittsburgh School of Medicine; Int. and Res., St. Margeret Memorial Hospital, Pittsburgh, PA. Would like to buy or start a solo practice or join a group in a medium to large-sized community. No OB. Write, PR/FP.

Oct. '90. Age 34. Presently in practice. Nat'l bds. AB cert. M.D., Medical College of VA; Int. and Res., Abington Hospital, Abinton, PA. Prefers group, associate or institutional type practice. Write, Jeffrey C. Ettinger, M.D., 501 Bryce Canyon Court, Petaluma, CA 94954.

INTERNAL MEDICINE

Aug. '90. Age 57. Licensed in Connecticut. Nat'l bds. AB cert. M.D., Boston University School of Medicine, Boston, MA; Int. and Res., Hartford Hospital, Hartford, CT. Prefers institutional or industrial type practice. JD Degree, New England College School of Law. Write, Charles A. Gundersen, M.D., 301 Tall Timbers Rd., Glastonbury, CT 06033.

Nephrology. July '90. Age 35. Licensed in Connecticut. FLEX. AB elig. M.D., Institute of Medicine & Pharmacy, Bucharest, Romania; Int. and Res., St. Barnabas Medical Center, Livingston, NJ; Fellowship, University of Medicine & Dentistry, New Jersey Medical School, Newark, NJ (Nephrology and Renal Pathology). Prefers group, assoc., institutional or solo practice. Write, Guy D. Sbar, M.D., 125 Elm St., Third Floor, Westfield, NJ 07090.

July '91. Age 32. Nat'l bds. AB cert. MD, Autonomus University of Guadalajara, Guadalajara, Jalisco; Int., Res., and Fellowship, College of Medicine & Dentistry of New Jersey—New Jersey Medical School, Newark. Prefers group or associate type practice. Write, Joseph L. Ianello, M.D., 72 Newark Ave., Apt. #5, Belleville, NJ 07109.

GENERAL SURGERY

Jul. '91. Age 33. Nat'l bds. AB elig. MD, SUNY at Stony Brook, Stony Brook, NY; Int., Booth Memorial Medical Center, Flushing NY; Res., Huron Road Hospital, Cleveland, OH. Prefers group or assoc. type practice in a medium to large-sized community. Write, Donna Vecchione, M.D., 27700 Bishop Park Dr., #402S, Willoughby Hills, OH 44092.

PSYCHIATRY

Immediately available. Age 49. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD, Osmania Medical College, Osmania University, Hyderabad, Andhra, India; Int., Osmania General Hospital, Hyderabad; Res., Manchester University, England; Fellowship, William S. Hall Institute of Psychiatry, Columbia, SC. Prefers part-time positions. Naimetulla A. Syed, M.D., Box 5525, Fairfield Hills Hospital, Newtown, CT 06470.

PAID CLASSIFIED ADVERTISING

All paid classified advertising orders, correspondence and payments should be directed to : CONNECTICUT MEDICINE, Classified Department, 160 St. Ronan St., New Haven, CT 06511, Tel. (203) 865-0587. The classified rates are as follows: $60.00 for 25 words or less; plus $1.00 for each additional word. For confidential answers, the cost is $3.00 per insertion, sent in care of CONNECTICUT MEDICINE. Ad copy, with payment, must be received no later than the first day of the month preceding month of issue.

FOR SALE by owner—On Connecticut river, in middle Haddam Historical District, small private community of 11 sites, some with magnificient river views. Just one hour from New Haven, 35 minutes from Hartford and Meriden and ten minutes from Middletown. New four bedroom, southwestern contemporary ranch and four bedroom Victorian contemporary colonial. Houses and eight choice lots with common beach frontage and approval for individual boat moorings. Ranch $455,000; Victorian $475,000; both rock bottom prices drastically reduced from original $570,000. Lots from $125,000 also drastically reduced. 10% down payment with below market rates, if good income; or make up own financial package. Prices and terms for SEPTEMBER ONLY. Tel: 389-5677.

AIM HIGH. Be an Air Force physician in a sophisticated medical environment. The benefits are excellent and vacation consists of 30 days with pay per year. Talk to an Air Force medical program manager about quality lifestyle and quality practice with a non-contributing retirement plan if you qualify. Learn more about becoming an Air Force physician. Call: USAF HEALTH PROFESSIONS. 1-800-432-USAF. AIR FORCE.

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Radiation Therapy for Ductal Carcinoma in Situ of the Breast

BRUCE G. HAFFTY, M.D., RICHARD E. PESCHEL, M.D., PH.D.,
DIMITRIOS PAPADOPOULOS, M.D., AND PRADIP PATHARE, M.D.

ABSTRACT—The optimal treatment for ductal carcinoma in situ (DCIS) of the breast is undefined. At three Connecticut hospitals 1) Yale-New Haven Hospital, New Haven; 2) Uncas-on-Thames Hospital, Norwich; 3) Norwalk Hospital, Norwalk, breast conservation therapy with lumpectomy followed by radiation therapy (RT) has been offered to women with DCIS as an alternative to mastectomy. From 1974 through 1987, 60 women with DCIS have been treated with RT. With a minimum evaluable follow-up of two years, a maximum follow-up of 15 years, and a median follow-up of 3.6 years, there have been no cancer-related deaths in the 60 patients. Four of the 60 patients (6.7%) developed a local breast recurrence but were salvaged with further surgical therapy (three patients with mastectomies and one patient with repeat lumpectomy). Only one patient (2%) has died of nonmalignant disease and the remaining 59 patients (98%) survived cancer-free. The five-year actuarial breast recurrence-free rate was 95%. These results suggest that breast conservation therapy with RT is a viable treatment option for women with DCIS.

Introduction

CONSERVATIVE surgery (lumpectomy) followed by radiation therapy (RT) is now an accepted option for early invasive breast cancer. The disease-free survival (NED) rates with radiation therapy are equivalent to the survival rates with mastectomy but with superior cosmetic results for stage I and II patients with invasive breast cancer.[1] Unfortunately, the treatment options for ductal carcinoma in situ (DCIS) of the breast are much less clearly defined. Despite numerous reports of excellent results with RT for DCIS, the exact role of RT for this subset of patients is controversial.[2-5] With the utilization of screening mammography, there has been a significant increase in the number of patients with DCIS diagnosed in the state of Connecticut. The proportion of noninvasive breast cancers diagnosed and treated at Yale-New Haven Hospital has dramatically increased from 3.3% in 1978 to 20% in 1988 (Fig. 1). This trend emphasizes the need for a critical evaluation of the various treatment alternatives for DCIS.

At Yale-New Haven Hospital (New Haven), Uncas-on-Thames Hospital (Norwich, Conn.), and Norwalk Hospital (Norwalk, Conn.), the treatment of early stage invasive breast cancer with RT has been utilized with increasing frequency over the past 20 years and is now a standard form of therapy for this disease. More recently, RT for DCIS has been offered as a viable alternative to mastectomy at these three institutions. For this reason, we have reviewed our experience with DCIS to determine if there should be any change in our treatment policy.

Methods

The radiation therapy charts of all patients with DCIS treated from 1974 through 1987 with conservative surgery and radiation therapy at Yale-New Haven Hospital, Uncas-on Thames Hospital, and Norwalk Hospital were retrospectively reviewed. Only patients with DCIS and no evidence of stromal invasion were included. The chart review produced a total of 60 cases with a minimum evaluable follow up of two years, a maximum follow-up of 15 years, and a median follow-up of 3.6 years. The patient population had a median age of 51 years, with range from 32 to 82 years. The surgical technique employed was a gross total removal of the mass or suspicious volume seen on mammography. No attempt was made to insure that the margins of resection were negative. An axillary dissection was performed on 15 patients (25%) and none of the patients received adjuvant systemic chemotherapy or hormone therapy. All of these patients had histologically negative nodes. The radiation therapy technique used tangential x-ray breast fields to a total median dose of 4600 cGy with an electron boost to the tumor bed to a total median dose of 6400 cGy at 200 cGy per fraction. Regional lymph nodes were treated in 14 patients (23%) in the early years of this study but this

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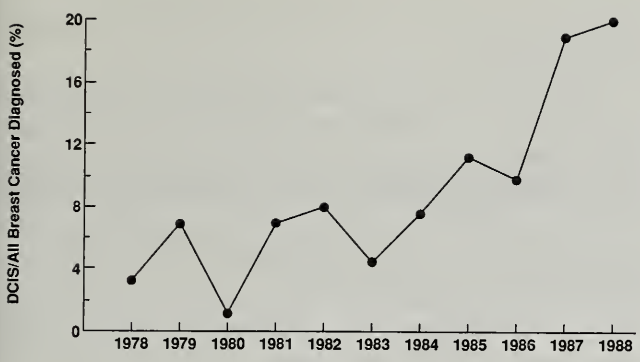

Figure 1
Incidence of DCIS at Yale-New Haven Hospital over the past ten years.

policy has been abandoned in recent years. Of special note is the fact that 45 patients (75%) had only mammographically detectable disease with no palpable mass. Patients were followed at regular intervals by both the referring surgeon and the radiation oncologist with annual mammograms and a minimum of two to three physical examinations per year.

Results

There have been no cancer-related deaths in the 60 DCIS patients treated with RT. Four of the 60 patients (7%) have developed a local recurrence within the irradiated breast. Three of the four recurrences had only pure intraductal histology and one patient had a small focus of microinvasion. Salvage mastectomy was performed in three of the four patients with recurrent disease and a repeat lumpectomy was performed in one patient. All four patients whose tumor recurred locally are alive without disease following salvage therapy. Only one patient (2%) has died, at age 82, of intercurrent, nonmalignant disease out of the total of 60 DCIS patients; the remaining 59 patients (98%) are alive without evidence of disease. Fifty-seven patients survived with a preserved breast resulting in a five-year actuarial breast recurrence-free rate of 95%. Table 1 summarizes the status of the 60 patients. The actuarial survival and breast recurrence-free survival rates are shown in Figures 2 and 3.

Table 1
Status of 60 DCIS Patients Treated with RT

Alive NED	59	98%
Dead NED	1	2%
Local recurrence	4	7%
Salvage mastectomy	3	5%
Salvage lumpectomy	1	2%
Breast preservation	57	95%

Key: NED - no evidence of disease

Discussion

The optimal treatment for DCIS is controversial. Mastectomy is the “gold standard” with which to compare other treatment modalities. From a review of 1,061 DCIS patients treated with mastectomy, Fowble found the percent of patients who were alive and free of disease to be 92% to 100% with a follow-up of 2.3 to 15 years.[2] A similar review of 357 DCIS patients treated with conservative surgery and radiation therapy showed that 98% to 100% of the patients were alive and free of recurrence and 90% to 98% had preserved breasts at 2.1 to 11 years follow-up.[2] Although the local recurrence rate was higher in the RT group (2% to 10%) compared to the mastectomy patients (0% to 4%) in the Fowble review, surgical salvage in the RT group was entirely satisfactory in that the overall survival was similar for the two groups.[2] The best objective data comparing mastectomy to RT for DCIS come from the randomized trial of the National Surgical Adjuvant Breast Project (NSABP). The NSABP found no significant difference in the number of treatment failures in the RT patients (4%) compared with the mastectomy patients (2%) and concluded that “...there are no compelling reasons why DCIS may not be treated with a cosmetically acceptable manner by...(lumpectomy with irradiation)... .”[3] Several other studies on the use of RT for DCIS show excellent long-term results at five to 10 years following breast conservation therapy.[4,5] Therefore, the available data do not support the conclusion that mastectomy is the optimal therapy for DCIS of the breast.

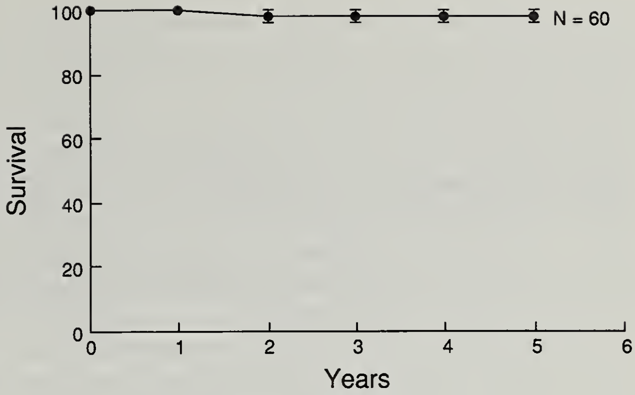

Figure 2
Acturial survival of 60 DCIS cases.

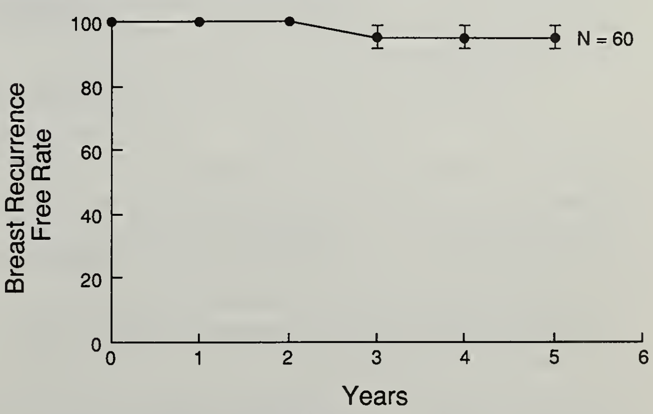

Figure 3
Acturial breast recurrence-free rate of 60 DCIS cases.

A third option for DCIS may be local excision alone (lumpectomy) without further therapy. However, the NSABP trial found a local recurrence rate of 23% in patients treated with lumpectomy alone compared with a recurrence rate of only 7% in patients treated with RT.[3] Several randomized trials (NSABP and EORTC) are currently underway comparing lumpectomy alone to lumpectomy plus RT. These trials should help define the indications for lumpectomy alone for DCIS.

Our results from three Connecticut hospitals indicate that five years following therapy, patients with DCIS may be treated with breast conservation RT and can be expected to achieve a 100% disease-free survival and a breast conservation rate of 95%. Although four of our patients developed local recurrence, salvage therapy was successful. Our local breast recurrence rate with successful surgical salvage is similar to the results of many other series using RT for DCIS as shown in Table 2. Longer follow-up will be required to see if these early favorable results are maintained at 10 to 20 years following therapy. It must also be emphasized that our DCIS patient population represents a favorable subgroup with 75% of the patients having no palpable tumor (mammographically detected).

Table 2

Local Recurrence Rates and Disease-free (NED) Survival following Salvage for DCIS Patients Treated with RT

Series (Ref)	*# Pts*	*Median Follow-up*	*Local Breast Recurrence Rate*	*NED Survival*
NSABP (3)	29	39 mos	7%	100%
Curie (4)	54	55 mos	6%	97%
Delouche (5)	18	132 mos	5%	—
Penn (2)	46	36 mos	4%	100%
Yale	60	43 mos	7%	100%

Key: Ref-reference, mos-months

Based on the early results from the three hospitals in the study and on a review of the literature, we conclude that breast conservation therapy with RT is a viable treatment option for DCIS. The importance of this report is related to the continued encouragement that we can offer to all women in Connecticut to seek regular screening mammography. The available data for both early invasive cancer of the breast and for DCIS suggest that breast conservation therapy with RT should be offered as a treatment option for all of these patients.

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UPDATE IN CEREBROVASCULAR DISEASE

Friday, 9 November 1990
Yale University School of Medicine
New Haven

Presented by:	Yale University Department of Neurology and Connecticut Neurological Society
Conference Chairman:	Lawrence M. Brass, M.D.
Faculty include:	Louis R. Caplan, M.D.; J.P. Mohr, M.D.; Michael S. Pessin; Bruce Ranson, M.D.; Alan H. Ropper, M.D.

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Role of MRI in Meningiomas: With and Without Gadopentetate

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ABSTRACT—Seventeen patients (15 newly diagnosed and two recurrent) with meningiomas were studied by magnetic resonance imaging (MRI) operating with 0.3, 0.5, and 1.5 Tesla magnets. In four patients gadopentetate dimeglumine was administered, following a noncontrast scan. In all the patients the tumors were isointense with the cortex at short relaxation and echo times (TR and TE) and became hyperintense with the increase in TR and TE on 0.3, 0.5, and 1.5 Tesla magnet systems. MRI correlated well with angiography in the detection of sagittal sinus thrombosis, and delineated tumor from edema as in computed tomography. Elimination of bony artifacts made detection of posterior fossa tumors easier with MR scanning. Gadopentetate dimeglumine shortened the scan time, displaying small tumors as well as sagittal sinus involvement to advantage. In these respects, we believe MRI is more effective than computed tomography in the diagnosis and management of meningiomas.

Introduction

MAGNETIC resonance imaging has gained rapid acceptance in evaluating intracranial pathology. As familiarity with the technology increases, information obtained from MRI will enhance diagnostic accuracy and anatomic delineation of intracranial lesions. MRI has still not secured a firm place in the diagnosis of meningiomas because most meningiomas have intensity patterns similar to the surrounding brain and are therefore indistinguishable from normal brain on shorter TR/TE sequences.[8,10,13,14] Computed tomography is considered more sensitive in diagnosing meningiomas.

The use of gadopentetate dimeglumine may circumvent this deficiency and shorten scan time. Enhancement with gadopentetate can be seen within three to four minutes and is known to persist as long as an hour.[3] In this study we studied sagittal sinus involvement with and without contrast, differentiated tumor from normal and edematous brain, and documented displacement of normal vasculature and proliferation of tumor vessels. We also studied the utility of MRI in treatment planning and follow up of these lesions.

Materials and Methods

This study includes 17 patients, 11 female and six male, ranging from 23 to 76 years in age. In all patients routine plain films, computed tomography, angiography, myelography (one case), and MR scanning were performed in that order. Preoperative MR scanning was done on 0.3, 0.5, and 1.5 Tesla permanent and superconducting magnet systems. In all patients spin echo (SE) pulse sequences were utilized. A preliminary single sagittal localizer film was obtained on every patient with a repetition time (TR) of 250 msec and an echo time (TE) of 30 msec. Multiple axial and in some patients, sagittal and coronal cuts were done. Slice thickness was 10 mm in all three planes.

Fifteen patients had newly diagnosed tumors, two were recurrent meningiomas, and one had undergone intracranial surgery for a chromophobe adenoma and presented with recurrent pituitary tumor as well as meningioma at the site of the incision. In four patients, gadopentetate dimeglumine was used. The initial precontrast scan in these patient was done with short TR/short TE and long TR/long TE sequences. The postcontrast scan was done with short TR/short TE sequence only. Two patients with foramen magnum meningiomas without disabling neurological deficit were treated nonoperatively. The remaining 15 patients had a total excision of their tumors.[7] (See Table 1).

Discussion

Fifteen percent of all intracranial tumors are meningiomas, and they are more common in women between the ages of 35 and 70 years. Generally they do not invade the brain, although they may erode osseous structures, but grow by expanding and eventually compressing as well as distorting the surrounding brain. Although meningiomas develop from the arachnoid layer and are grossly well demarcated from the brain, MR scanning may fail to reveal these tumors because they have the same proton density as the surrounding cortex. (Fig. 1a-b) Initial concern has been the efficacy of MRI in detecting meningiomas. Lately with the introduction of higher field strengths (such as 1.5 Tesla) and gadopentetate dime-

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Table 1

CT AND MRI FINDING

Patient #	*Age*	*Sex*	*Location*	*Clinical Presentation and Treatment*	*CT Findings*	*MR Findings*
1.	70	M	Left frontal at craniotomy site	Incidental to work-up for recurrent chromophobe adenoma	Hyperdense mass	Isointense on short TR/TE; hyperintense on long TR/TE.
2.	68	F	Left parasagital	Right hemiparesis and apraxia	Hyperdense with massive edema	MR done in 8 echoes to differentiate tumor from edema; sagittal sinus thrombosis seen.
3.	60	F	Foramen magnum	Dizziness, occipital headache; tongue deviation	CT 1 yr before admission - no lesion seen. Repeat CT - questionable foramen magnum lesion.	Isointense lesion with short TR/TE; increased intensity with long TR/TE.
4.	38	M	Foramen magnum	1 year H/O persistent pain behind right ear; and diminished sensation (pin-prick) left side of the body.	Myelogram showed total block Cl	MR showed mass extending from Cl into the lower third posterior fossa; demonstrated on long TR/TE.
5.	68	M	Foramen magnum	Ataxia, (only VP shunt done)	Inconclusive	Demonstrated right auterolateral foramen magnum mass with no change in subsequent 6 monthly follow-up.
6.	38	F	Lesion extending CP angle to C6	Recurrent meningioma with mild dysphagia	CP angle lesion demonstrated entire extent of lesion not well seen	Lesion extending from CP angle down to the bifurcation of right common carotid.
7.	76	M	Left parietal meningioma	Seizures	Enhanced lesion with moderate edema	Multiple echoes for tumor edema differentiation.
8.	42	M	CP angle	Behavioral changes only	CP angle lesion. Middle fossa extension not seen.	Lesion in CP angle extending into the middle fossa, supplied by AICA.
9.	30	F	Right parieto-occipital	Seizures	Right parieto-occipital lesion	Right parieto-occipital lesion with areas of void indicating hypervascularity Sagittal sinus compression.
10.	61	F	Right parasagital	Headache	Right parasagital hyperdense lesion	Parasagittal lesion with sagittal sinus thrombosis.
11.	51	F	Tuberculum Sellae	Left eye blindness	Tuberculum sellae enhanced lesion	Tuberculum sellae lesion seen on long TR/TE.
12.	40	M	Right olfactory groove	Frontal lobe signs	Right Subfrontal hyperdense lesion	Right subfrontal hyperintense lesion.

Table 1
CT AND MRI FINDINGS (Continued)

13.	45	F	Planum sphenoidale	Headache, anosmia	Hyperdense, subfrontal lesion	Increased intensity with increased TR/TE; arcuate bowing of white matter; CSF cleft.
14.	60	F	Right parasagittal	Parietal lobe signs	Right parasagittal hyperdense tumor	Right parasagittal tumor enhanced with Gadopentetate. Encasement of SSS, with no definite luminal invasion.
15.	42	F	Tuberculum Sellae	Left Temporal hemianopsia	Hyperdense lesion	Involvement of optic chiasm and no involvement of carotid arteries or cavernous sinus.
16.	60	F	Tuberculum Sellae	Headaches	Hyperdense lesion	No involvement of carotids, cavernous sinus or optic chiasm.
17.	48	M	Tentorial (multiple meningimas with fibrous dysplasia)	Dizziness	Hyperdense lesion. Left tentorial edge	Eliminated recurrence in previous surgical site because signal intensity showed fat (mucocele). Gadopentetate showed the petrous ridge on T_1 weighted image.

All MRI Scans done with SE technique.

Cases 1 to 6 done on .5 Telsa; 7 to 13 done on 1.5 Telsa; 14 to 17 done on .3 Tesla.

Cases 14 to 17 done with and without contrast.

glumine, MRI may even become a primary imaging modality in the near future. In our patients, in the initial noncontrast studies, meningiomas were indistinguishable from the brain on short relaxation time (TR = 250 msecs), and short echo times (TE = 30 msecs). The intensity of the tumors increased with an increase in TR/TE, particularly with the 1.5 Tesla scanner.

Edema Versus Tumor

Brain edema can be classified as vasogenic, cytotoxic, and interstitial.[2] In vasogenic edema, frequently encountered in brain tumors, there is a breakdown of the blood brain barrier, with, therefore, increased extracellular water content. In MRI, therefore, peritumoral edema appears as an intense signal in T2 weighted images because edematous brain becomes hyperintensive with each succeeding echo. In two of our patients with increase in TE, delineation of edema and tumor was clearly seen. Tumors, however, diminished in intensity, displaying mild hyperintensity on the final or eighth echo. (Fig. 2a-b-c)

Sagittal Sinus Thrombosis

Parasagittal meningiomas probably arise from arachnoid cell rests along the superior sagittal sinus and are adherent to the falx. Although meningiomas generally only compress the brain, they may involve the overlying bone and adjacent sinuses. The superior sagittal sinus in parasagittal tumors is frequently either compressed or invaded. In all four of our patients the sinus was involved to some degree. Historically angiography has been necessary to display the sinus involvement and this involvement is best appreciated on lateral projections. MRI on the other hand, displays the involvement well by showing the absense of the normal flow void on coronal slices. Both angiography and MRI failed to distinguish compression from the actual invasion in one our patients. In one patient to whom we administered gadopentetate dimeglumine, sinus compression without invasion was clearly demonstrated (Fig. 3 a-b).

Posterior Fossa Meningiomas

MRI is helpful in demonstrating caudal and cephalad extension of meningiomas in the posterior fossa (Fig. 4). In case 8, extension of the tumor into the middle fossa was picked up by MRI alone. Case 4, presented a different dilemma, wherein myelography failed to show the upper extent of the tumor because of a complete block at C1. MRI demonstrated the extension into the posterior fossa with clarity (Fig. 5a-b). Unlike computed tomography, therefore, MRI is not hindered by streak artifacts generated at the base of the skull by dense bone.[5,6,9,10,11] Compact bone generally give low or no signal at all. By eliminating bony artifacts, lesions of the posterior fossa (particularly of the foramen magnum) are well visualized by MR scanning. Multiplanar imaging without having to reposition the patients and without resorting to invasive procedures such as myelography, metrizamide cisterno-

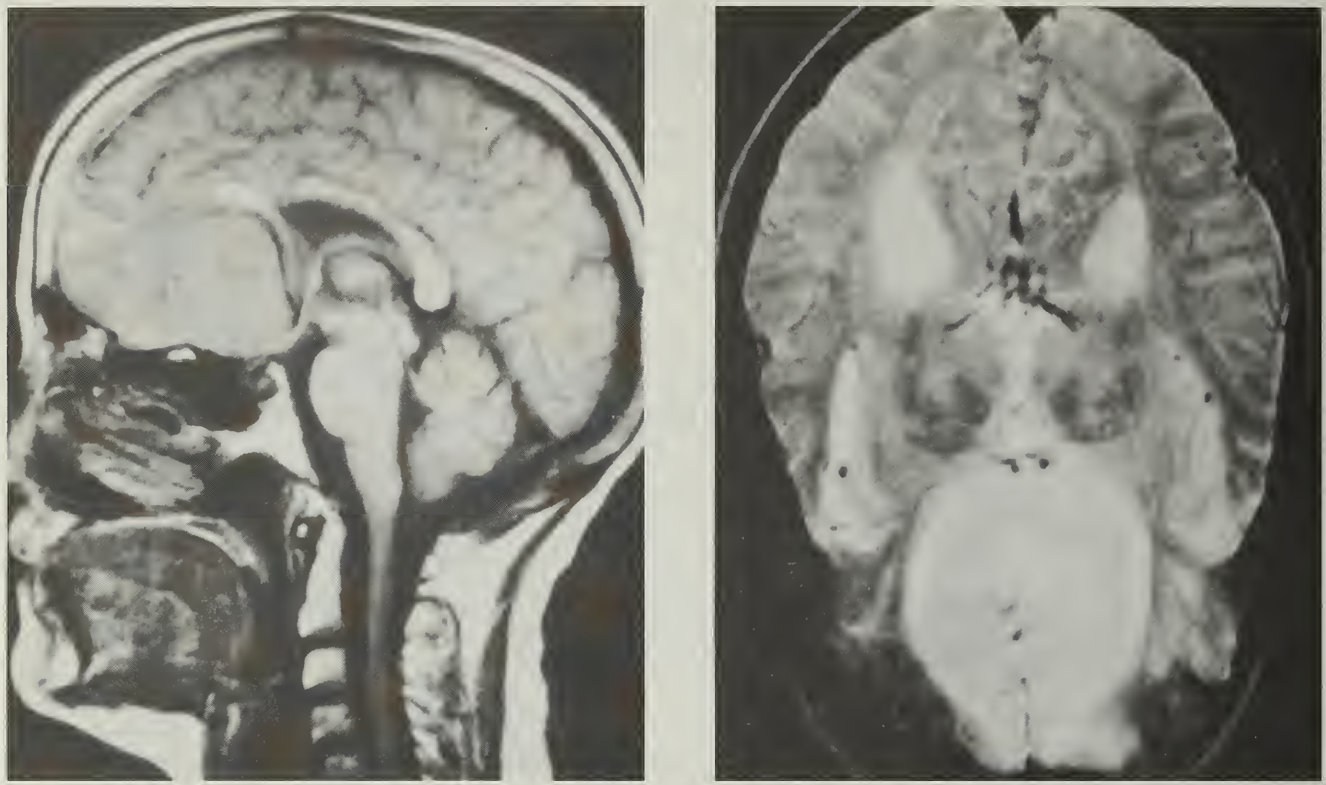

Figure 1a

Figure 1b

MRI in sagittal plan with a short TR/TE 250/30 msec) showing the planum sphenoidale tumor isointense with the brain; the same tumor, in the axial plane, shows an increase in intensity on a long TR/long TE (1600/100) sequence. Note the white matter buckling in Fig. 1a and the hyperintense CSF cleft in Fig. 1b (Case No. 13)

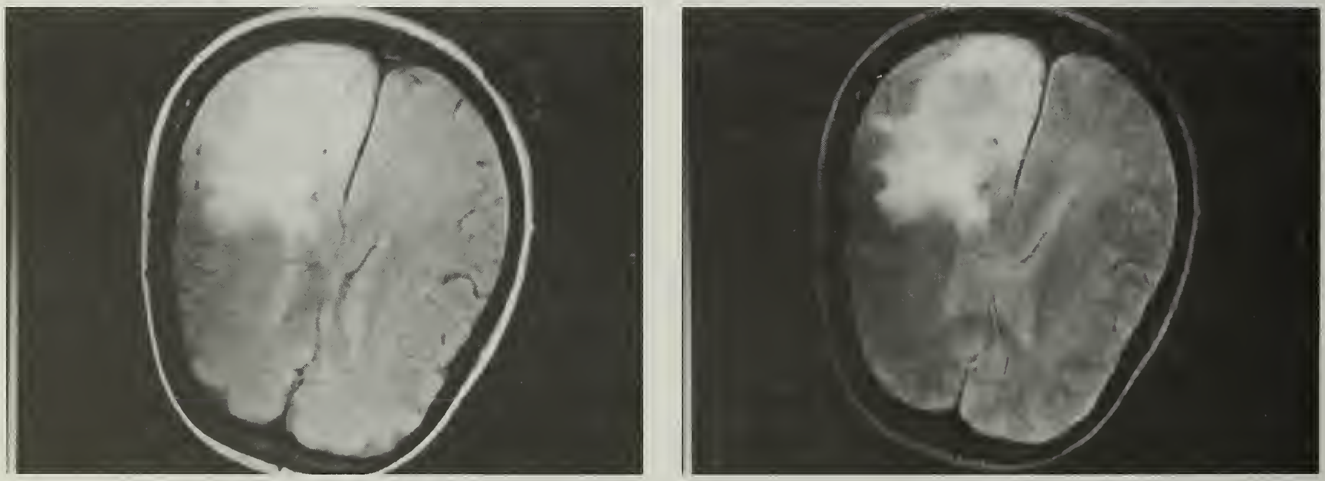

Figure 2a

Figure 2b

Tumor and edema are well differentiated in multiple echoes with a TE increments of 30, 60 and 120 msecs and TR of 2100 msecs. (Case No. 2)

graphy, or angiography is another major advantage of MRI in delineating posterior fossa lesions.[4] Two of our patients with foramen magnum meningiomas underwent MRI scanning at six monthly intervals in order to follow tumor growth. This proved to be a satisfactory method of serial visualization and had the advantage of being noninvasive. Although MR scanning and computed tomography are equally effective in diagnosing and managing supratentorial lesions, MR imaging proved superior in lesions of the skull base, posterior fossa, and craniovertebral junction in our study. Pre and postoperative assessment can be done with minimal discomfort to the patient since it does not entail the use of catheters or myelography.[9]

Vascular Supply

It is important for the neurosurgeon to be able to gauge vascularity before surgery. Magnetic resonance, unlike angiography, displays vascular flow noninvasively (Fig. 6 a-b). Since rapidly flowing blood causes no signal on MR, normal as well as neoplastic vessels appear as a signal void in comparison with tumors which gain in intensity with each succeeding echo and remain hyperintense in comparison to the cortex. Furthermore, anatomy can be displayed in coronal, axial, or sagittal planes

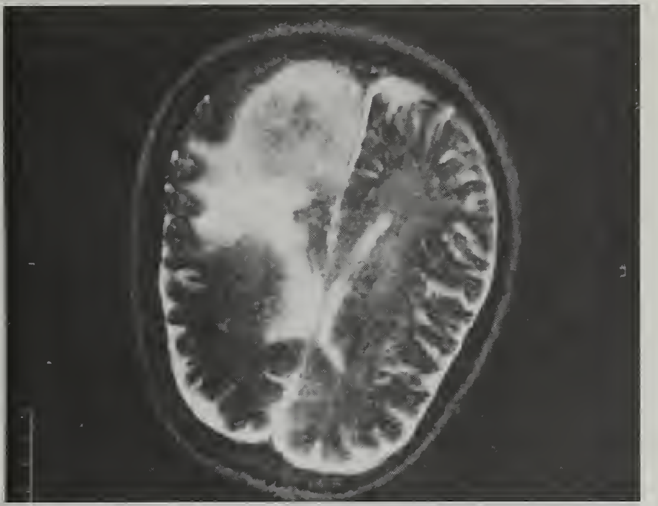

Figure 2c

helping the neurosurgeon to visualize the tumor and its vascularity in three dimensions. Currently, angiography is still necessary in pinpointing the exact vascular supply of these tumors; particularly in cases where embolization is being considered. Ten percent of meningiomas show calcification;[1] the inability of MRI to display calcification is an important limitation. Hyperostosis may be adequately demonstrated in MRI because of moderate increase in intensity and by virtue of increased thickness of the calvarium.[14] Nonvisualization of calcification or hyperostosis may be a problem; however, other features, such as the ones mentioned earlier in the text, arcuate bowing of white matter, and the high intensity CSF cleft between the tumor and brain (indicating extraaxial mass) (cases 13 and 14), more than offset those deficiencies.

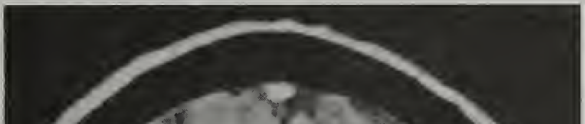

Figure 3a

Sagittal sinus thrombosis seen on first echo without contrast. (TR/TE 1600/100 msecs) and compression without invasion seen with gadopentetate (TR/TE 700/37 msecs). (Cases No. 2 and 14)

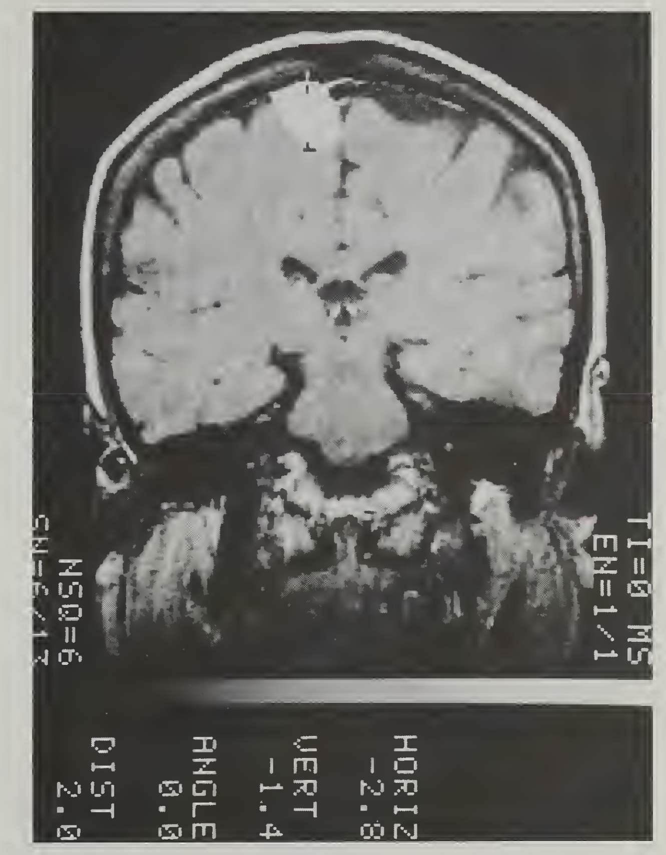

Figure 3b

Contrast MRI

In two of our patients with parasellar lesion, gadopentetate was particularly helpful in excluding cavernous sinus, optic chiasma, and carotid artery involvement (Fig. 7 a-b). Intrasellar meningiomas, although rare, may be yet another place for the use of the contrast agent to distinguish the former from the pituitary tumors. In case 17 we were able to rule out recurrence at the site of initial surgery (frontal) because of signal intensities as well as gadopentetate use. However, the patient had a new lesion in the region of the petrous ridge which was operated upon. (case 17) We, therefore, feel that MRI has the potential to eclipse computed tomography as a primary imaging modality as well as diminish if not eliminate the use of angiography in diagnosing and managing meningiomas.[10,11,12]

Acknowledgements

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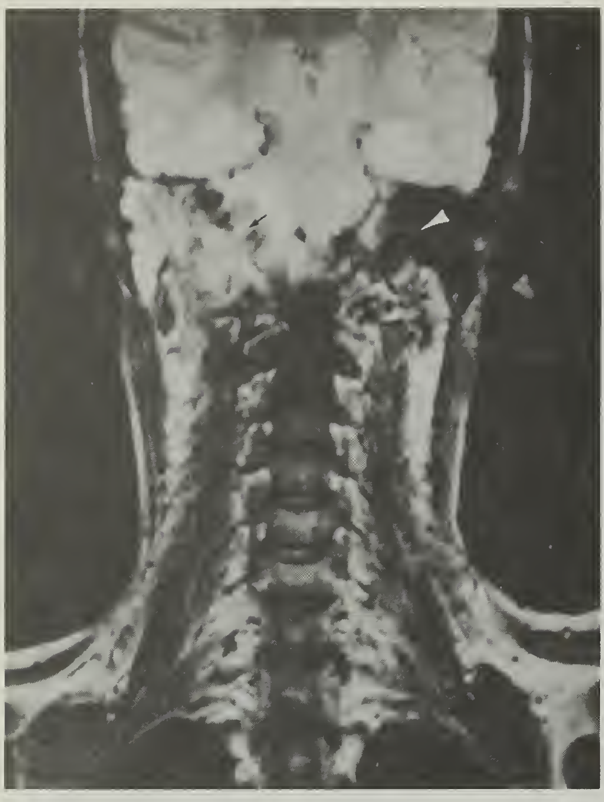

Figure 4

Cerebello-pontine angle meningioma extending into the foramen magnum and into the upper cervical region (arrow). Note the normal signal void from bone on the opposite (left) side (arrow head). (Case No. 6).

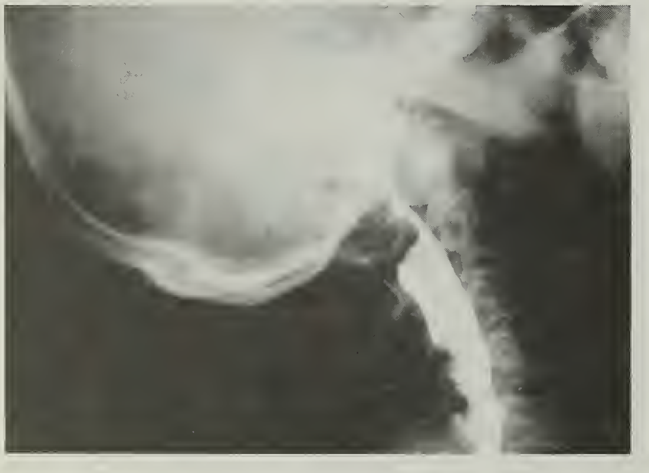

Figure 5a

Isovue myelography showing a total block at C1 and MRI demonstrating the posterior fossa extension in a foramen magnum meningioma. (Fig. 5B from Wagle, V.G., et al, Neurosurgery, Vol. 21, No. 5. p. 622-626, 1987.)

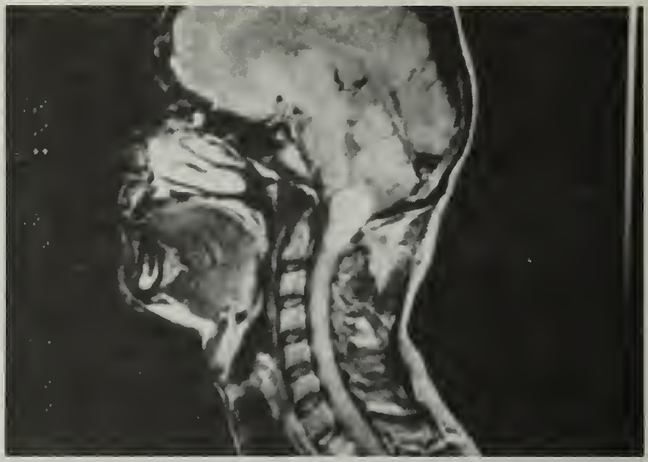

Figure 5b

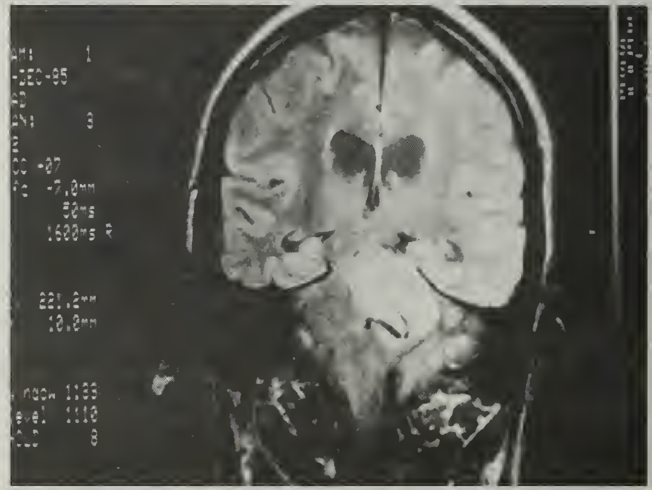

Figure 6 (a-b) Coronal and axial scans demonstrating signal void from rapid flow in the AICA which supplies the cerebello-pontine angle meningioma. (Case No. 8)

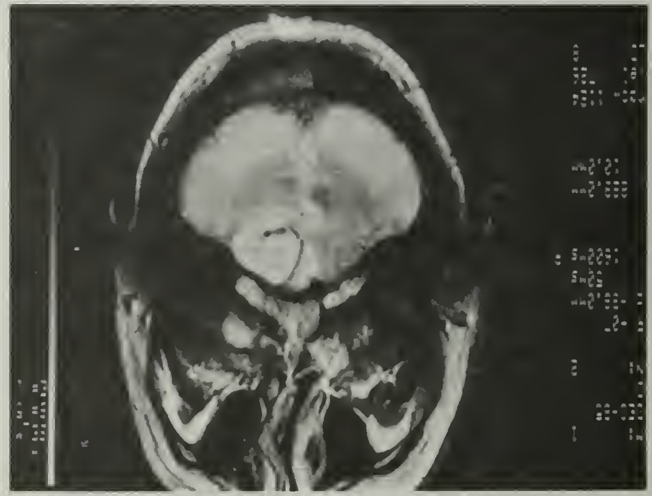

Figure 6b

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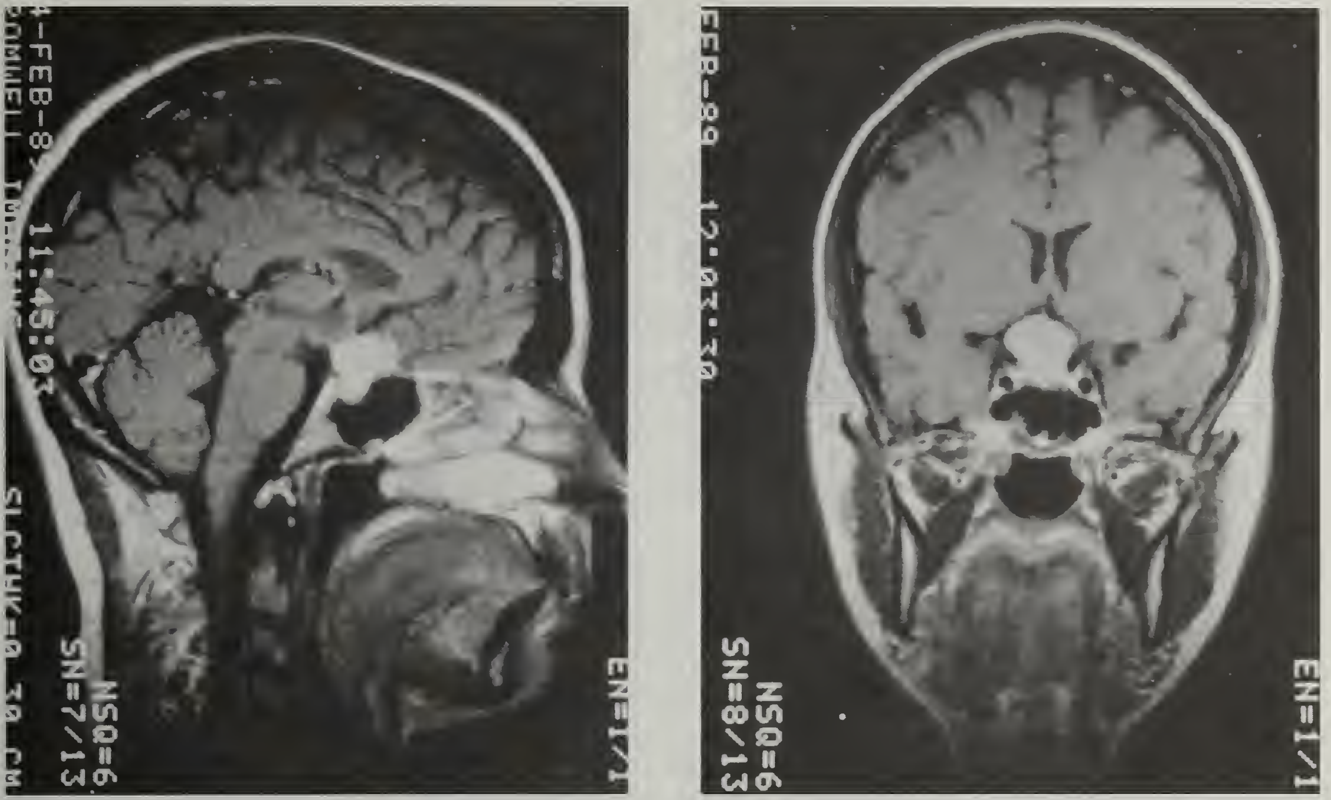

Figure 7 (a-b)

Gadopentetate dimeglumine MRI in sagittal and coronal planes showing non-involvement of the carotids, but compression of the optic chiasm on the left.

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Colocolic Intussusception in a Three-Year-Old Child Caused by a Colonic Polyp

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AND DIANE GALLO VANESS, M.D.

ABSTRACT—Colocolic intussusception is an uncommon cause of pediatric intestinal obstruction in North America; 95% of cases are ileocolic in location, with an equal percentage in which no pathologic lead point is evident on barium enema or laparotomy.[1] In the last 20 years less than 3% of approximately 2,500 reported cases of intussusception originated in the colon.[2-10] In a significant number of these cases juvenile polyps were identified as leading points. The majority of juvenile polyps occur in the rectosigmoid colon within the reach of a standard pediatric sigmoidoscope. These tumors most often cause painless hematochezia. Occasionally, juvenile polyps may grow large and serve as lead points for colocolic intussusception when located in the proximal colon. Pediatric patients presenting with documented colocolic intussusception should suggest the possibility of a colonic polyp or other mass lesion. Careful physical examination and barium studies should provide important diagnostic clues. Treatment is aimed at removing the lead point in patients presenting with intestinal obstruction. Colonoscopic polypectomy performed by an experienced endoscopist may serve as an alternative to surgical removal of the polyp. We report a case in a three-old-child of colocolic intussusception caused by a colonic polyp, and review some of the salient features of this clinical entity.

Case Report

In August 1988 a three-year-old black female presented to the emergency department with a history of intermittent, crampy abdominal pain and vomiting of two weeks duration. She was found to have a low-grade fever of 38° C, but an otherwise negative physical examination. An initial complete blood cell count, sedimentation rate, and a flat plate abdominal series were negative. The patient was discharged with instructions to be given a clear liquid diet, but during the next 72 hours was observed by her parents to spit up blood and complain of abdominal pain. Her parents also described two episodes of "jellylike" blood tinged stools. She returned to the hospital and clinical examination revealed an ill-appearing child doubled over with pain. The patient had a fever of 38.3° C, pulse 108, respiratory rate 24, and a blood pressure of 108/68. Her abdomen was not distended, but a linear, firm, palpable mass was present in the left upper quadrant. Rectal examination revealed a pliable mass within the vault, and her stools were positive for occult blood. Flat films of the abdomen showed obstruction at the level of the splenic flexure without evidence of intraperitoneal air or pneumatosis (Figure 1). A barium enema identified a colocolic intussusception and a wide-based polypoid lesion proximal to the splenic flexure (Figures 2 and 3). The intussusception was reduced after two trials of hydrostatic reduction and glucagon administration.

Follow-up studies postreduction revealed a persistent filling defect (Figure 4). Colonoscopic polypectomy was attempted, but was unsuccessful, largely because of the wide-base configuration of the polyp and its location within a redundant loop of colon. Small fragments of tissue were retrieved and pathologic examination was consistent with a juvenile polyp. An abdominal flat film once again revealed a filling defect in the splenic flexure. The patient subsequently underwent a partial colon resection beginning at the midtransverse colon and ending at the splenic flexure. She tolerated the procedure well, was discharged, and has had an uneventful postoperative course with complete resolution of her symptoms.

Discussion

The clinical features of colocolic intussusception are, for the most part, indistinguishable from ileocolic intussusception. Patients may present with abdominal colic, emesis, rectal bleeding, and a palpable abdominal mass. The major differentiating feature is the presence of a palpable abdominal mass within the topographical plane of the colon.[11] Most patients with colocolic intussuscep-

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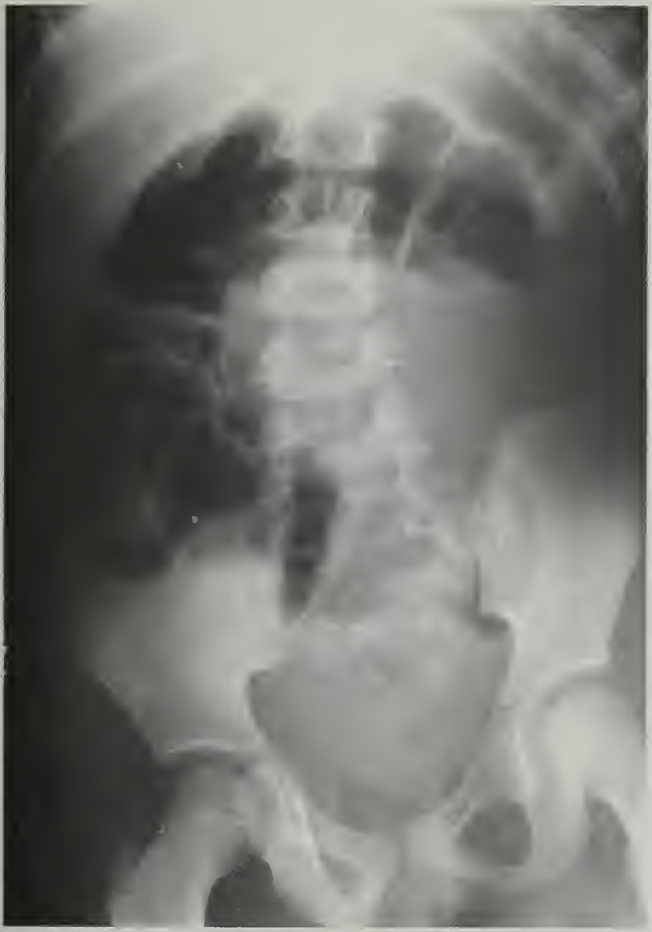

Figure 1

Flat plate abdominal x-ray reveals dilated loops of colon and a paucity of air distal to the splenic flexure. These radiological findings are consistent with obstruction distal to the splenic flexure.

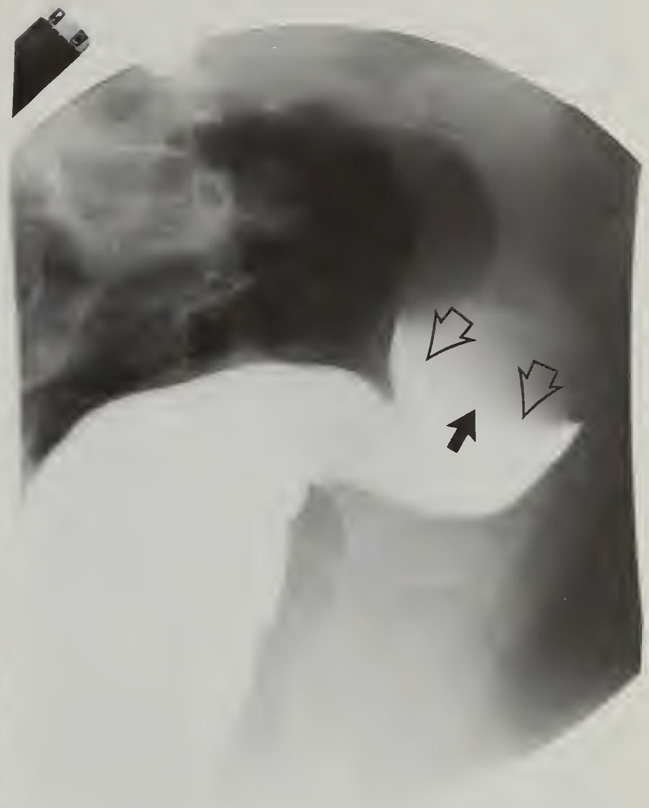

Figure 2

A coned-down view of the splenic flexure reveals the presence of a colocolic intussusception. The convex proximal radiolucent area represents the intussusceptum and is the central invaginated segment of bowel (open arrows). The concave radiopaque distal portion of the bowel is the intussuscipiens and represents the external segment (solid arrows).

tion due to a colonic polyp tend to be older than 24 months at presentation.

The natural history of juvenile polyps is autoamputation without the patient requiring surgical or medical intervention. Histologically these lesions are thought to represent a hamartomatous or inflammatory process.[12] A small number of patients present with prolapse of the polyp through the anus, and associated crampy abdominal pain. These symptoms are most likely due to tethering on the polyp with invagination of the proximal attached bowel into the distal segment of colon during peristalsis. Large polyps located in the proximal colon are more likely to cause colocolic intussusception when these conditions are met. Ippolito et al reported the occurrence of nine juvenile polyps as leading points among 33 cases of colocolic intussusception reported over a 15 year period.[2] A flat plate abdominal radiograph contrast barium enema should confirm the diagnosis. The presence of a persistent filling defect following hydrostatic reduction is another helpful clue to making the diagnosis of a juvenile polyp (Figure 4).

Asymptomatic polyps do not come to medical attention. When patients present with symptoms, colonoscopy is indicated for polyp removal and histologic diagnosis. In contrast to adenomatous polyps, the development of carcinoma in a juvenile polyp is unlikely.[12] Because of the small number of patients presenting with colocolic intussusception prospective studies are not available to document the efficacy of hydrostatic barium reduction with respect to recurrence. Barium reduction, if successful in these patients, may temporarily reduce the intussusception, but the retained polyp remains a potential lead point for recurrent intussusception or continued bleeding. The primary justification for colonoscopic poltomy in symptomatic patients is the possibility of recurrent intussusception or the likelihood of rebleeding. Our patient required surgical treatment because attempted colonoscopic polypectomy failed, and a persistent filling defect was still evident on follow-up barium studies. Review of the literature suggests that intussusceptions caused by colonic polyps or other mass lesions can rarely be reduced by hydrostatic barium enema and these patients often require laparotomy.[5,7]

In summary, pediatric patients presenting with documented colocolic intussusception should raise suspicion of the possibility of a colonic polyp or other mass lesion. Careful physical examination and barium studies should provide important diagnostic clues. Treatment is aimed at removing the lead point in patients presenting with intestinal obstruction. Colonoscopic polypectomy performed by a skilled endoscopist may serve as an alternative to abdominal surgery for removal of the polyp.

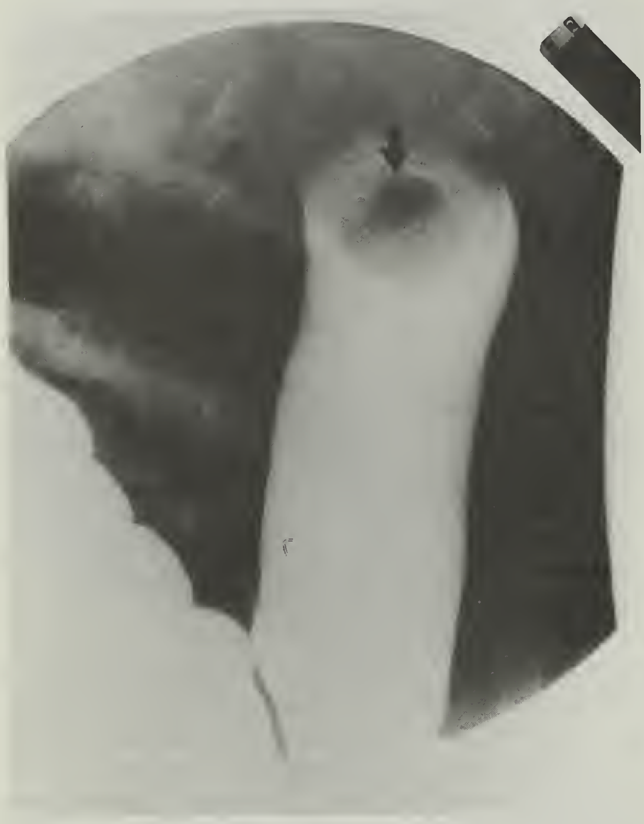

Figure 3

A large polyp is seen at the splenic flexure during barium reduction (arrow).

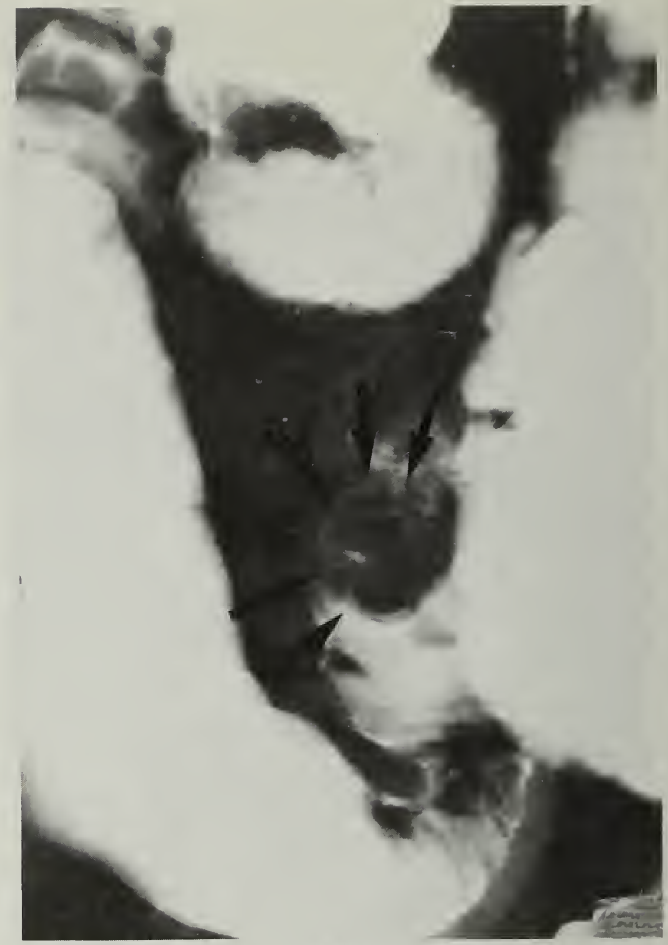

Figure 4

A postreduction film reveals a large filling defect consistent with a polyp (arrows).

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Important Advances in Clinical Medicine

Chest Diseases

The Scientific Board of the California Medical Association presents the following inventory of items of progress in chest diseases. Each item, in the judgement of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in chest diseases that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Chest Diseases of the California Medical Association, and the summaries were prepared under its direction.

Inhaled Treatment of Asthma

THE topical delivery of metered-dose inhaler (MDI) drugs is currently regarded as optimal for the treatment of asthma. The standard dosages of most agents are two to four puffs from an MDI three or four times a day, whereas inhalant solutions of bronchodilators are usually given in dosages that may be ten times as large. Recently there has been a trend towards using an appropriately increased number of puffs of an MDI (usually with a spacer added) for emergency department and inpatient therapy for acute asthma in place of jet-nebulizer aerosolization.

The increasing death rate of asthmatic patients has led to concerns about the role of sympathomimetic aerosols. In New Zealand, the potent aerosol bronchodilator, fenoterol, has been cited as potentially hazardous, but no other MDI preparation has been implicated. Recently airway reactions to the use of metaproterenol sulfate (Alupent) MDI were found to be the result of a change in the adjuvant, and this problem has been resolved by restoring the original formulation.

Corticosteroids are used by some authorities to provide cornerstone therapy for the inflammatory changes that characterize asthma. The appropriate doses and number of treatments a day for various MDI products are controversial, however. It is probable that increased dosage would be effective in some persons with asthma who respond inadequately to standard dosing with inhaled steroids, although the inconvenience and expense are major obstacles. It is claimed that flunisolide is effective if given twice a day, and it is probable that beclomethasone dipropionate and triamcinolone would be equally effective if given twice rather than three or four times a day.

In the outpatient management of asthma, most experts prescribe MDI delivery of a β_2-selective bronchodilator, using increased doses if necessary. A spacer can be advantageous, but some patients prefer the new inhaled powder form of albuterol. A steroid MDI with a spacer can be added, but considerable individual experimenting may be needed to establish the optimal dosing for each patient. Younger patients may benefit from using cromolyn sodium and older ones with a component of chronic obstructive pulmonary disease should try ipratropium bromide. Oral therapy in patients with chronic asthma has a secondary role, but an oral agent should be introduced—choosing from slow-release theophylline or albuterol, or prednisone—if the aerosol regimen becomes too complex or demanding. For a competent adult patient, there is no justification for prescribing a powered nebulizer or an exotic aerosol drug delivery system to be used at home.

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Lasers in Pulmonary Treatment

IN the past decade lasers have been developed for the treatment of tracheobronchial obstruction. Evidence gathered by many investigators indicates that the neodymium-YAG [yttrium-aluminum-garnet] laser is most helpful in providing rapid and safe palliative relief of obstructed large airways—trachea, main stem, and lobar bronchi—due to intraluminal benign or malignant lesions. Laser therapy may provide palliative relief in an asphyxiating patient for whom no therapeutic alternative previously existed.

The electromagnetic or photon energy of lasers is absorbed by tissues and dissipated as heat-causing destruction. In the case of the neodymium-YAG laser, energy is transmitted through a thin, flexible quartz fiber that easily passes through the biopsy channel of a flexible or rigid bronchoscope. The procedure is done in an operating department or its equivalent under full anesthetic control, preferably through a ventilating rigid bronchoscope, and generally requires less than two hours of operating time and two days' stay in a hospital.

Those intraluminal lesions that are most technically responsive are short, polypoid, and only partially obstruct a major airway. Alternatively, extensive or predominantly peribronchial (extraluminal) lesions as detected by bronchoscopy and chest computed tomography are not easily palliated.

Most symptomatic patients who require laser treatment have primary or metastatic lung cancer that has recurred or cannot be controlled despite previous or concurrent surgical therapy, radiation therapy, or chemotherapy. In selected cases, however, patients having severe dyspnea, wheezing, stridor, cough, hemoptysis, or unresolved pneumonia or atelectasis may require immediate initial laser treatment because of life-threatening symptoms associated with a benign or malignant lesion in a major airway. Symptomatic relief from asphyxiation in a patient with endobronchial malignancy can be achieved for an average of six months.

Laser therapy is clinically justified for the initial treatment of benign tracheal stenosis due to an outgrowth of a fibrous web or diaphragm in symptomatic patients with severe air flow limitation who have not responded to mechanical dilatation. It can offer excellent palliative relief and in some cases be curative. Optimal results may ultimately require additional surgical resection or a Montgomery tube. Tracheomalacia is not an indication for laser therapy.

We have been impressed with the frequent incidence of malignant or benign lesions of the trachea or main-stem bronchi (or both) in symptomatic patients that go undetected by chest roentgenograms. Chest computed tomography, pulmonary function studies, and bronchoscopy may be necessary in unresolved cases. Current research for the detection of unsuspected endobronchial malignant tumors involves fluorescence imaging using injected hematoporphyrin derivative and krypton ion laser. In addition, photodynamic ablation therapy may be achieved by using an argon-pumped dye laser causing irreversible tissue oxidation.

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Lung Transplantation

NINE years after lung transplantation was shown to be feasible in dogs, the first human lung transplantation was done in 1963. In the next two decades, rapid developments in the field of solid organ transplantation took place, but the feasibility of lung transplantation was held back by difficulties with immunosuppression, bronchial healing, and infection. In spite of that, in the mid-1980s successful lung transplantation in humans became a reality in Toronto, Canada, where the first procedure was carried out. Since that time several centers have begun doing both single- and double-lung transplants with excellent results. It is now possible to offer lung transplantation in appropriately selected and treated candidates with a 60% to 70% one-year survival figure. There are several four-, five- and six-year survivors in the lung transplantation program from Toronto. The availability of more selective and powerful immunosuppressive agents including cyclosporine, OKT3, and other monoclonal antibodies is now making appropriate and selective immunosuppression possible. A better understanding of posttransplantation infection with advances in the diagnostic techniques has led to the rapid recognition of these infections and their treatment, leading to better results.

Current indication for single-lung transplantation vary slightly from center to center. At the moment, common indications for single-lung transplantation include pulmonary fibrosis, pulmonary emphysema from whatever cause, Eisenmenger's syndrome with simple intracardiac defects, and primary pulmonary hypertension. Double-lung transplantation is indicated in patients who have end-stage bilateral septic disease and thus require replacement of both lungs to prevent postoperative infection. Such diseases as cystic fibrosis and bronchiectasis are common indications of double-lung transplantation in 1990. The criteria for acceptance into the program include an appropriate psychosocial history and a lack of severe diseases in other organ systems.

Lung transplantation offers several advantages over heart-lung transplantation, but most particularly offers a feasibility of donation that does not occur with the more common and more established heart-lung transplantation. The organ allocation system in the United States provides that when a patient is on the waiting list for a status I heart, the organ will be allocated to that recipient. Because of this, there are frequently hearts donated with the lungs not being used, if only heart-lung recipients are being screened. When a lung transplant patient is on the waiting list, however, the lungs are then usable for that patient. It is possible to obtain from a single donor two single-lung transplant preparations and a heart transplant for a third patient. This has been carried out in several centers throughout the world.

At a recent seminar on lung transplantation, it became apparent that more than 200 lung transplantations have been done worldwide in the past year or two with the survival figures as mentioned. It is obvious that this is no longer an experimental procedure but one that is a therapeutic necessity in many patients who are otherwise condemned. In the future, we will see the indications widen and the procedure being done in many centers in much the same way as the clinical activity in heart and liver transplantation has changed in the past ten years.

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Transtracheal Oxygen Therapy

GIVING supplemental oxygen has been shown to improve survival in persons with chronic obstructive pulmonary disease (COPD) who have significant hypoxemia. In the National Institutes of Health Nocturnal Oxygen Therapy Trial, patients with a Pa_{O_2} of 55 mm of mercury or less (oxygen saturation ≤ 88%) when stable or a Pa_{O_2} of 56 to 59 mm of mercury (oxygen saturation of 89%) in association with polycythemia or cor pulmonale were randomly assigned to receive either nocturnal oxygen or continuous oxygen therapy. Those advised to use oxygen continuously actually used it an average of 19 hours per day and lived considerably longer than those using oxygen only at night. Oxygen therapy can also enhance the exercise capacity in persons with hypoxemia.

Administering oxygen through a nasal cannula (nasal prongs) has been the conventional mode of delivery in outpatients, but the delivery of oxygen through a transtracheal catheter was reported almost a decade ago. Initial concerns that transtrachael catheters would commonly become infected and cause chronic irritation have not been confirmed. The advantages of the transtracheal administration of oxygen over that of a nasal cannula include eliminating the irritation of the nose and ears from the nasal prongs and tubing, being able to instill a saline solution through the catheter to help liquefy thick secretions, being able to reduce the flow rate required to maintain a satisfactory blood oxygen level to half or a third of that using a nasal cannula, and eliminating the obviously visible nasal cannula. The reduced quantity of oxygen needed allows patients to use smaller portable oxygen systems, enhancing the ease of mobility. Patients with transtracheal catheters are more likely to receive the recommended amount of oxygen at night, as the oxygen connection to the catheter is much less likely to become displaced than is a nasal cannula.

Possible concerns with regard to the use of transtracheal catheters for administering oxygen are that it requires a physician trained in the technique of catheter placement; it is more expensive than a nasal cannula to introduce initially and to replace; it requires some skill on the part of the patients and their families to clean and maintain: and it is prone to the attachment of mucous plugs to the catheter, which can provoke coughing and cause airway obstruction.

Most patients who have compared the two routes of administration clearly prefer the transtracheal catheter to a nasal cannula for continuous oxygen therapy. As more physicians become experienced in placing these catheters, this mode of oxygen delivery will likely become much more common.

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Pharmacologic Management for Stopping Cigarette Smoking

ALL pharmacologic intervention for stopping cigarette smoking are thought to work by diminishing nicotine withdrawal symptoms after the patient stops cigarette use. There is no "magic bullet" that will make a patient stop smoking. All medication available, both those proved effective and those that are experimental, require a patient motivated to stop smoking and a physician motivated to assist the patient.

Nicotine replacement therapy remains the cornerstone of pharmacologic management. The only practical way of providing nicotine replacement currently is through the use of nicotine polacrilex (Nicorette). Numerous published studies show that nicotine replacement therapy using the medication can produce significant abstinence results, not only at the end of treatment (73% versus 42%) but one to two years after treatment began (44% versus 12%). Such results can only be achieved as part of a planned, professionally supervised program. Physician prescription cannot simply be phoned in; rather, the prescription must include the proper instruction in medication use and professional follow-up. Otherwise, nicotine replacement therapy is ineffective.

A critical step for achieving effective results with nicotine replacement therapy is providing patients with proper and complete instruction for medication use. Patients should anticipate using medication for three to six months. If they smoke a pack a day, they should use 12 pieces of nicotine polacrilex a day; if a pack and a half, 16 pieces a day; and, if two packs, 20 pieces a day. The medication should be tapered off slowly over two to four months. Patients should understand that nicotine polacrilex cannot be used while drinking beverages such as tea, coffee, soft drinks, milk, or alcohol, as the acid pH of these beverages completely blocks the release of nicotine from the medication. Present data show that the nicotine replacement therapy works synergistically with behavioral interventions and will boost the effectiveness of the behavioral intervention twofold to threefold. This conclusion applies whether the behavioral intervention is simply a physician advising a patient to stop smoking or intensive behavior modification.

Several new technologies for delivering nicotine—transdermal patch and nasal spray—are undergoing clinical testing, with initial, promising results for the patch at the end of a three-month treatment period. Other, totally different pharmacologic interventions are in early clinical testing. Trials of the use of clonidine hydrochloride (Catapres) and of doxepin hydrochloride (Sinequan) have shown excellent and significant results at the end of a four-week treatment period. Results in women using clonidine versus placebo tablets at the end of four weeks' treatment were excellent (72% versus 15%), but results in men were disappointing (47% versus 50%). A second clonidine study, however, failed to replicate those results, finding no difference in either abstinence rates or withdrawal symptoms. Clinical trials with adrenocorticotropic hormone (ACTH) and fluoxetine are underway. The use of clonidine, doxepin, ACTH, and fluoxetine must be regarded as experimental at this time. Agents that may prove useful in the future include central nicotinic receptor blockers, excitatory amino acids, serotonin (5-hydroxytryptamine)-receptor antagonists, and calcium channel blockers.

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Ventilator Use in the Inpatient Management of Chronic Obstructive Pulmonary Disease

MECHANICAL ventilation in patients with chronic obstructive pulmonary disease is indicated when conservative measures such as the treatment of precipitating causes, the administration of oxygen, the removal of secretions, and bronchodilator therapy have failed. Clinical signs suggestive of respiratory failure include tachypnea—respiratory rate more than 30 breaths per minute—prominent accessory respiratory muscle use, and asynchronous motion of the thorax and abdomen during inspiration. This has been called thoracoabdominal paradox and is seen when the respiratory muscles are working excessively against high loads. The severity of the respiratory failure can be evaluated by measuring arterial blood gas values. Hypoxemia can be managed by giving supplemental oxygen. The major criterion for ventilatory support is the severity of acute respiratory acidosis. Generally if the pH falls below 7.25, mechanical ventilation is indicated. Hypercapnia with a compensated acidotic base state—pH 7.4—is not an indication for mechanical ventilation.

The major goals of ventilation are to provide adequate gas exchange while the precipitating cause of the respiratory failure can be managed. Many authorities now recommend that ventilatory support should also aim to rest the ventilatory muscles. The basis for this suggestion is that fatigue of the respiratory muscles is considered a complicating factor in the pathogenesis of respiratory failure. Recovery from the acute episode and facilitation of weaning may depend on providing adequate rest to the respiratory muscles. This thinking has influenced the modes of ventilation now in use.

Until recently, the major modes of ventilation available consisted of control, assist-control, and intermittent mandatory ventilation. The original promise of intermittent mandatory ventilation to improve patient ventilator synchrony and prevent the development of posthypercapnic metabolic alkalosis during ventilation has not been realized. Furthermore, it has not been shown to be superior in weaning patients from mechanical ventilation. Assist-control ventilation provides only partial rest to the respiratory muscles. If the respiratory drive is high, considerable work is expended by the patient.

Pressure support ventilation is a new mode of ventilation whereby a constant airway pressure is applied to the airway during spontaneous breathing or while using the intermittent mandatory ventilation mode. The patient is able to control tidal volume and inspiratory flow rates. The higher the level of pressure support applied, the larger the tidal volume and minute ventilation and the greater the reduction in patient energy expenditure. Low levels of pressure support—4 to 8 cm of water—are considered helpful in overcoming the resistance of artificial airways and ventilator circuits. When these levels of pressure support are used in intubated patients during spontaneously initiated breaths, it may be easier to evaluate the patient's ability to sustain spontaneous ventilation after extubation. Ongoing research will clarify the role of pressure support in improving patient ventilator synchrony, alleviating respiratory muscle fatigue, and facilitating weaning.

Once mechanical ventilation is started, the initial ventilator settings, rate, and tidal volume should be adjusted to maintain a normal pH. In cases of acute hypercapnia, carbon dioxide levels can be reduced rapidly to baseline to normalize the pH. In patients with chronic respiratory acidosis—a rapid reduction in the $Pa{CO_2}$ will cause an acute respiratory alkalosis superimposed on the present acid-base state and should be avoided. In this state, seizures and death can occur. Patients should be "reset" at their maintained $Pa{CO_2}$ before being weaned from the ventilator.

Higher inspiratory flow rates decrease inspiratory muscle work, reduce the physiologic dead space, improve arterial oxygen tension, and provide increased exhalation time and therefore a reduction in intrinsic positive end-expiratory pressure (PEEP). Intrinsic PEEP occurs with airway obstruction, delayed exhalation, and a consequent increase in the functional residual capacity. Successive breaths arrive prematurely before the previous expiration is complete, and intrathoracic pressure does not return to atmospheric levels, remaining persistently elevated, as when external PEEP is applied. Intrinsic PEEP is exceedingly common in patients with obstructive airways disease. Under normal circumstances, the pressure gauge on the ventilator records atmospheric pressure during expiration and reads zero even in the presence of high levels of intrinsic PEEP. The level of intrinsic PEEP can be measured by occluding the expiratory valve at the end of exhalation and noting the pressure on the ventilator gauge before the next inhalation. Intrinsic PEEP also causes distortion of the measurement of central venous pressure and lung compliance.

The mortality of chronic obstructive pulmonary disease in patients who require mechanical ventilation for acute respiratory failure ranges from 21% to 42%. About 3% of those who survive require long-term mechanical ventilation.

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Pulmonary Disorders Caused by Illicit Drug Use

ILLICIT drugs may be administered intravenously, intranasally, orally, or through inhalation by smoking. Pulmonary disorders associated with the intravenous and intranasal abuse of drugs have been well documented. Recent attention has focused on the effects of inhaling these drugs. There have been a number of recent reports of pulmonary disorders attributed to the inhalation of marijuana, cocaine, and methamphetamines.

Inhaling marijuana smoke may result in injury to the conducting airways as a result of noxious gases, oxidants, and other toxins in the particulate phase. Pathologic effects include ciliary dysfunction, inflammation of airway walls, squamous cell metaplasia, and peribronchial fibrosis. The large number of toxic substances produced during pyrolysis is similar to that produced during cigarette smoking. The physiologic effects of habitual abuse include increased airway resistance, ventilation-perfusion abnormalities, and decreased gas exchange surface, resulting in symptoms of cough, dyspnea, wheezing, and diminished exercise tolerance. The concentrations of some carcinogens and other toxins are greater in marijuana smoke than with tobacco, which may place regular marijuana users at a high risk for bronchogenic carcinoma.

Cocaine hydrochloride must be converted to the pure alkaloid form ("crack") before it can be heated, volatilized, and inhaled. Abusers may have chronic cough, dyspnea, acute pulmonary hemorrhage, or, rarely, pulmonary edema. Patients may present with acute bronchospasm indistinguishable from an acute asthmatic attack from other causes. A decrease in the diffusing capacity of the lung for carbon monoxide (D_Lco) is the most commonly cited physiologic abnormality. The underlying mechanisms of decreased D_Lco from cocaine use are not well understood. Long-term cocaine smoking may cause a syndrome of fever, cough, and radiographic findings of diffuse pulmonary infiltrates. The pathophysiology of this clinical syndrome is postulated to be either from the direct action of cocaine or from volatile hydrocarbons. Dyspnea may also be a result of a pneumothorax caused by smoking cocaine and is thought to be due to the Valsalva's maneuver commonly practiced by these smokers.

Methamphetamine hydrochloride must first be highly purified to have the volatility necessary for inhalation. The purified form has a crystalline appearance and is commonly called "ice." This inhalation drug problem is epidemic in Hawaii and on the West Coast. The data on pulmonary complications, both acute and chronic, are limited. Physiologically, methamphetamine is a direct central nervous system stimulant that also increases sympathetic nervous system activity and serum catecholamine concentrations. Smoking "ice" results in central nervous system symptoms of euphoria, agitation, and psychosis and cardiovascular symptoms of hypertension, tachycardia, and arrhythmias. Although a direct effect of methamphetamine on lung tissue has not yet been proved, acute dyspnea and cough are associated. Because smoking "ice" is a relatively new phenomenon, it is possible that some yet-undescribed pulmonary or radiographic finding may occur.

In patients with unexplained cough, dyspnea, or radiographic findings, clinicians should consider illicit drug abuse. A urine immunoassay can detect cocaine or methamphetamine metabolites as long as two days after use.

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Mechanical Respiratory Support at Home

LONG-TERM home ventilator support is an attractive option for many patients with severe stable respiratory failure due to a variety of neuromuscular, musculoskeletal, and pulmonary diseases. Guidelines and standards now have established reasonable indications, selection criteria, protocols, and the team approach needed to prepare for home care and for follow-up.

When ventilator support is initiated electively, patients are able to adjust more easily, with assistance from trained family members. Elective ventilator support is usually needed less than 12 hours a day. Although tracheostomy has been used frequently, noninvasive methods should be considered first, such as positive pressure ventilation using a nasal mask or mouthpiece; negative pressure ventilation using a cuirass, iron lung, or various other techniques; and a rocking bed. Recent experience with the nasal mask suggests its advantages in effectiveness and in avoiding upper airways obstruction. The cost involved in ventilator assistance on an elective basis is within reach of usual resources for many patients, about $20 to $40 a day.

In contrast, patients in intensive care units on discharge require long-term ventilator support, usually 12 to 24 hours a day. A tracheostomy is often needed both for ventilation and to remove secretions. Patients may have multiple impairments and limited functional performance. Because more complex care is required, patients are more often dependent on others for most of the 24 hours. Paid caregivers are generally required to assist the family. The financial costs—about $150 to $300 a day— are greater than most patients can arrange, unless third-party or public funds are available, but are still less than the costs for hospital care. Adjusting to the unexpected and catastrophic situation is difficult for patients and families.

Hospital discharge preparation is a multidisciplinary team process that can enable most of these patients to go home or to another community alternative site. Experienced medical centers can assure a quality of care in the home environment that is comparable to that in a hospital. Two-year survival can be more than 70% for patients with neuromuscular disorders and more than 50% for patients with chronic obstructive pulmonary disease. Care must be coordinated with community agencies, a medical equipment company, and emergency services including the utility company, fire department, and a hospital emergency department. Patients generally prefer their quality of life at home when compared with the hospital setting; they can live in ways that are more personally satisfying and socially useful.

The challenges and burdens for a patient's family and the community home care resources can be enormous, particularly when care is complex and carried on for several years. The funding and community services required for these patients and their families need to be improved. Properly planned, however, long-term home respiratory support can be rewarding for patients, their families, and the medical team directing care.

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Inhaled Pentamidine Therapy for *Pneumocystis carinii* Pneumonia

INHALED pentamidine therapy is now indicated for the primary and secondary prophylaxis of *Pneumocystis carinii* pneumonia in patients with human immunodeficiency virus infection. Both primary prophylaxis, for persons with fewer than 2×10^6 per liter (200 per μl) CD4 (helper) lymphocytes who have not had an episode of *P carinii* pneumonia, and secondary prophylaxis, for those patients who have had a previous episode of the disease, are administered through a Respirgard II jet nebulizer (Marquest, Englewood, Colorado) at a dose of 300 mg of pentamidine isethionate once a month. The regimen is the result of a recent study of inhaled pentamidine as secondary prophylaxis for *P carinii* pneumonia that found giving 300 mg once a month superior to 30 mg or 150 mg given every two weeks. Relapse rates at 18 months were approximately 10% in patients receiving 300 mg once a month compared with a 65% relapse rate at one year in historical controls.

Toxicity from inhaled pentamidine has been minimal and limited to bronchospasm, preventable with the previous administration of inhaled bronchodilators.

Relapses of *P carinii* pneumonia after inhaled pentamidine therapy tend to occur in the apices of the lungs and possibly are related to poor drug deposition in those areas. Spontaneous pneumothorax (probably due to rupture of pneumatocles in the apices) and extrapulmonary pneumocystosis have been reported in patients receiving inhaled pentamidine, raising a concern that pneumocystosis is in fact a systemic process and not one localized to the lung. Therefore, a combination of parenteral and local (inhaled) prophylaxis may be required. Two ongoing prophylaxis trials will further define the use of inhaled pentamidine. One compares using 300 mg with 600 mg of inhaled pentamidine once a month and the other compares using inhaled pentamidine, 300 mg once a month, with using the combination drug, trimethoprim and sulfamethoxazole, one double-strength tablet twice a day, or dapsone, 50 mg twice a day.

Studies are also in progress comparing the use of inhaled pentamidine with that of trimethoprim-sulfamethoxazole for the treatment of mild to moderate *P carinii* pneumonia. Standard therapy for this disease in patients with the acquired immunodeficiency syndrome has consisted of trimethoprim-sulfamethoxazole (as 15 mg per kg per day of the trimethoprim component in three to four divided doses given orally or intravenously) or of pentamidine isethionate (4 mg per kg per day as a single intravenous infusion). Unfortunately, both of these regimens are associated with substantial toxic reactions, and as many as 50% of patients will require a change or modification of therapy because of toxicity. Nausea, vomiting, fever, rash, neutropenia, and elevated aminotransferase levels occur with the use of trimethoprim-sulfamethoxazole. Parenteral pentamidine use is associated with hypotension, hypoglycemia, azotemia, pancreatitis, and neutropenia. Alternatively, inhaled pentamidine therapy has not been associated with significant systemic toxicity.

These observations led to a trial of inhaled pentamidine, 600 mg per day for 21 days, as sole therapy in 15 patients with *P carinii* pneumonia. Of 15 patients, 13 completed treatment and 14 patients survived an admission to hospital. A patient who had concomitant disseminated tuberculosis died during the second week of therapy. This encouraging study resulted in a comparative trial of inhaled pentamidine, 600 mg a day, and trimethoprim-sulfamethoxazole, 15 mg per kg a day of the trimethoprim component, in approximately 250 patients. Patients were treated for 21 days in a randomized, double-blind manner. Findings from this study are pending the analysis of data. Until then, inhaled pentamidine as therapy for *P carinii* pneumonia should be considered experimental.

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Creosote: A Short History of Its Medicinal Uses

JOHN S. HALLER, JR.

TODAY, when one happens to come across the term "creosote," it is usually in the context of one of the preservative oils, carcinogenic and hazardous to human health. However, this was not always the case, as perusal of older medical journals and texts attests. There one could find creosote prominently touted as part of the armamentarium of medical practice and, like many of the early "Samsons" of the materia medica, prescribed with great confidence for a host of different diseases and symptoms.[1,2,3,4,5] For many, especially in rural America, creosote was the poor man's cure-all. Country folk took small doses of creosote or "Maltine with Creosote" and "Maltine with Wine of Pepsin," for vomiting and chronic diarrhea, albuminuria, neurasthenia, jaundice, general debility, gastroenteritis, nervous dyspepsia, and diabetes mellitus. Families also used it as a gargle, an ointment for ringworm and various cutaneous affections, and as a "specific" in the early stages of tuberculosis and pneumonia. [6(201),7]

Creosote, from the Greek *kreas*, flesh, and *sozo*, preserve (meaning "I preserve the flesh"), is produced from the distillation of wood tar, especially beechwood, and has long been used as a preservative. Meat dipped into a 1% solution becomes dry and hard on exposure to air, thus arresting putrefaction. In its most common form, creosote is a mixture of guaiacol, creosol, and other phenols, including carbolic acid. Of these, guaiacol is the most abundant, representing 60% to 90% of the whole. When pure, creosote is a colorless, oleaginous liquid, slightly greasy to the touch, highly refractive, having a penetrating, smoky odor, and a burning, caustic taste. The physiological effects of creosote closely resemble those of carbolic acid but it is considerably less toxic than the latter to the system.

In 1832 the German naturalist Karl Reichenbach (1788-1869) introduced creosote as a specific for phthisis, believing that the product of crude pyroligneous acid or wood tars exercised an antiseptic action in the lungs. Because of creosote's known property of preserving animal matter, Reichenbach also applied it topically in a 2% solution for patients with suppurating wounds, burns, itching, gangrene, osseous caries, ulcerative tumors, cancrum, and syphilitic ulcers.[8] Following his announcement in the *Bulletin general de therapeutique* of Paris, other medical journals made note of the discovery and, within three years, a number of observers, including E. Mignet,[9] J. Dietrich, [10] and J.F. Fremauger[11] had added a long list of diseases in which the virtues of creosote were extolled. Although English physicians remained skeptical, German and French surgeons prescribed creosote internally for stomach disorders and externally for rheumatic and neuralgic pains, indolent sores, and as a sedative for toothache.[12,13,(340-1),14(682-3),15,16]

The skepticism exhibited by Irish physicians was understandable since, decades earlier, they had been assaulted by the virtues of tar-water. The English philosopher and bishop, George Berkeley (1685-1753), while living in Rhode Island, had learned of the medicinal properties of tar-water and recommended it as a preventive against smallpox, scurvy, falling sickness, palsy, chronic diseases of the skin, as a cleanser of the capillaries, and as a general panacea for life's infirmities.[17] "Take tar water morning and evening," advised the celebrated John Wesley, founder of Methodism, and author of *Primitive Physic; Or an Easy and Natural Method of Curing Most Diseases* (1747), "this is a tried medicine for Old Age and will probably renew the Strength for some years."[18(66)] Reichenbach's consideration of the active principle of tar-water as a specific for phthisis simply follows the drug's lineal descent from the early panegyric to the uses of tar-water.[19]

Unlike many of his countrymen, however, English physician John Elliotson, M.D. (1791-1868), believed in the virtues of creosote and undertook a series of experiments in 1835 at St. Thomas's Hospital in London. Testing creosote on cases of phthisis and epilepsy, he discovered that the medicine acted as a stimulant; however, when the

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dose exceeded two or three drops, the patient suffered nausea, vomiting, vertigo, and headache. If, on the other hand, patients began with doses of one or two drops, they were eventually able to endure 20 or more drops without unpleasant effects. Indeed, one of Elliotson's patients steadily augmented her dosage to 40 drops. Typically, he mixed creosote with a little mucilage before suspending it in water at a ratio of one drop per ounce of water.[20(219-20)]

In his trial with phthiscal patients, Elliotson initially directed his patients to mix creosote with water. This apparently proved "perfectly unsuccessful," causing him to experiment with inhalation. Here again, he found no particular effect except an occasional diminution of cough and expectoration. On the basis of this evidence, however, Elliotson concluded that where "only a single ulcer, or but a small number, exist in the lungs, and there is no disposition to further tubercular formation, it is very beneficial." He likewise found it helpful in the treatment of all types of chronic bronchitis, especially in conditions of profuse secretion without inflammation. Similarly, he claimed that the inhalation of creosote helped in cases of asthma.[20(220-1)]

In his experiments with epilepsy, Elliotson discovered that some patients had milder seizures and at longer intervals after taking creosote, but that the disease usually returned with the same level of intensity and, on occasion, was actually aggravated. Nevertheless, creosote's "tranquillizing effect" encouraged him to recommend it in neuralgia, hysteria, and extreme nervousness.[20(221-2)]

Elliotson tested the drug's effectiveness during the Asiatic cholera epidemic in London in 1835, directing that his patients at St. Thomas's be given creosote to arrest their vomiting. Although all died, Elliotson observed that the creosote had effectively subdued the gastric mucosa, leading him to conclude that no other medicine compared with it in arresting nausea and vomiting.[19(227)]In still other experiments, Elliotson found that creosote worked wonderously on ulcerated surfaces and even for diabetes. [20(232-34)] He also injected a weak solution of creosote up the nostrils of two patients who had contracted acute glanders and chronic farcy from a horse. Interestingly, he remarked to his readers that, although his patients responded well to the treatment, "I need not say that the disease has always hitherto proved fatal in the horse."[20(237)]

By the late 1830s, physicians were regularly prescribing creosote to remove crustaceous formations on the scalp, in the treatment of bowel complaints of all kinds, in chronic bronchitis, and to reduce the pain of broken and decayed teeth. Others used it to wash wounds and to treat gangrene. In the latter case, physicians prescribed undiluted creosote, followed by a plaster composed of equal parts of Burgundy pitch, opium, camphor, and oil of turpentine. When the line of separation formed, physicians encouraged the healing process with a creosote ointment.[21,22(235-6)]

The internal use of creosote underwent a partial eclipse at mid-century because of its lack of purity and the not infrequent notices in medical journals of accidental poisoning deaths in which victims mistook creosote for alcohol.[23,24] Notwithstanding this brief setback, individuals such as Thomas Inman, M.D., called attention to the inhalation of the vapor of creosote combined with steam for phthisis and bronchitis.[25] In addition, Elliotson's earlier experiments with creosote during the 1835 cholera epidemic did not go unnoticed during the subsequent epidemic of 1850. However, to the dismay of physician Benjamin W. Richardson, the epidemic passed before he could test the effects of the drug. He subsequently had the opportunity to try creosote in the treatment of ordinary diarrhea and concluded that "there is no astringent remedy half so useful in. . .cases of profuse purging." Although Richardson recommended creosote for children, he cautioned colleagues to use the smallest amounts, usually one-fourth to one-eighth of a drop for children under two years.[26]

In the diarrhea of infants and adults, Joseph Adolphus, M.D., of Atlanta, claimed to have used creosote successfully throughout the second half of the nineteenth century. Adding 10 to 16 drops of creosote to a pint of water, he directed his patients to take one to two fluid ounces before, after, and between meals. In some instances, he prescribed the medicine in a mucilage of gum acacia and a pleasant aromatic preparation of licorice.[27(300-301)]

During the American Civil War, physicians in the South and border states prescribed creosote for tuberculosis, carbuncle and furnuncle, as an intestinal stomach and mucous membrane cleanser, and as an antiseptic dressing and bath for battle wounds. In the fall of 1862, at the Hickory Street Post Hospital in St. Louis, C. H. Hughes, M.D., used a creosote drip on open wounds to counteract septic infection. In addition, he applied a creosote solution on compound fractures and following amputation. The secret of its success, observed Hughes, was not in the large doses suggested by earlier physicians, but rather in small, well-diluted doses which made for easy assimilation and vital stimulation. Hughes anticipated by more than a half century the Carrel-Dakin drip process in treating infected wounds in World War I.[28]

Most physicians found little difference between creosote and carbolic acid, viewing them as more or less the same substance. Potter described carbolic acid as a phenyl alcohol derived from the distillation of coal tar, and creosote as a phenol mixture composed largely of guaiacol and creosol. He then went on to state that both had the same physiological effects and therapeutic indications. Actually, the differences were very real from both the physiological and toxic points of view. Carbolic acid was employed almost exclusively as a local application while creosote was used both internally and externally.[29(735)]

Creosote rivaled carbolic acid in its antiseptic action. When taken internally, both caused burning of the gullet and stomach, vertigo, faintness, unconsciousness, collapse, blackish urine, and cardiac depression. Interestingly, nearly all the commercial beechwood creosote on the market during the second half of the nineteenth century was adulterated with carbolic acid. As a result, many physicians prescribed the German creosote sold under the name of "coal tar creosote" in the mistaken belief that it was the beechwood creosote minus the carbolic acid. Actually, the large doses which physicians prescribed in the nineteenth century caused pharmaceutical manufacturers to cease labelling and marketing "coal tar creosote," for fear that the patient might take a large dose of impure phenol instead.[13(341-2)]

In 1876, following Inman's example, Imlay recommended creosote in an atomized solution for the relief of phthisis; this was followed quickly by favorable reports by Bouchard and Gimbert.[7] Bouchard observed that patients increased in weight 30 to 40 pounds after being treated with creosote and that 55% of his cases derived benefit from the drug.[30] In 1879, Sommerbrodt saw its value as an antitubercular remedy and, as a result of his trials, reported a 27% success rate out of 5,000 cases treated with the drug. He theorized that, after free administration of creosote, the system became saturated with the bactericidal powers of the drug which, in turn, destroyed the tubercular nodules.[13(342)] According to Klemperer, however, the improvement which followed the administration of creosote to phthiscal patients was really due to the drug's bitter tonic effect in stimulating the mucous membranes of the stomach and intestines.[31(115)] Others such as Daremberg complained that doctors had unjustifiably embarked on "creosote orgies" with fruitless results.[30]

Prior to the 1890s the use of creosote in pulmonary lesions had been little favored outside of Germany and France where Sommerbrodt, Rosenthal, Bouchard, and Gimbert had produced an array of clinical evidence in support of the remedy. Except for Isaac B. Yeo in his *Manual of Medical Treatment or Clinical Therapeutics* (1893) and a few other stalwarts, the drug inspired little confidence among English physicians. Among Americans, Beverly Robinson, M.D. (1844-1924), valued creosote as the result of prescribing it over many years in the form of inhalation and internal usage.[32] Nevertheless, Robinson's claims were not uniformly received. James K. Crook, M.D., instructor of clinical medicine and physical diagnosis at the New York Post-Graduate Medical School and Hospital, experimented with the drug over a period of six years, administering it in almost every variety and stage of phthisis. He concluded that, while creosote relieved much of the expectoration, promoted the appetite, and stimulated digestion, it did not appear to modify the course of phthisis. In all cases where the creosote was given in place of other forms of medication (tonics, stimulants, cod-liver oil, etc.), the progress of the disease "was always in the wrong direction." Indeed, his best results occurred when he administered creosote in combination with cod-liver oil, extract of malt, and other forms of tonic medication. From this evidence, Crook recommended creosote in cases requiring a "pulmonary disinfectant" or when accompanied by feeble appetite, for flatulence, and in other situations of "fermentative action in the stomach and intestines."[13(344)]

According to Austin Flint (1812-1886) in his *Treatise on the Principles and Practice of Medicine* (7th ed., 1894), creosote inspired the greatest confidence among physicians and patients by diminishing cough and expectoration, increasing the patient's strength and weight, improving appetite, and reducing the frequency of night sweats.[30] His finding, announced in 1889, resulted in further studies undertaken by J. A. Wessinger, M.D., of Ann Arbor who treated phthisical patients with Flint's continuous inhalation method. On the basis of these trials, Wessinger reported that patients gained in weight, cough and expectoration lessened, and night sweats sometimes ceased entirely. Wessinger chose to use pure beechwood creosote internally as well as by inhalation; he observed that the medicine acted as a harsh irritant and that his patients had to be kept under continual observation for fear of toxicity or damage to the kidneys.[33(4431)]

To explain its action on phthisis, physicians subscribed to several different theories. Some suggested that creosote promoted sclerotic changes and favored cicatricial development around the phthisical areas. Another theory suggested that creosote formed compounds in the blood which antagonized the development of tubercular bacilli. In support of this theory, Sommerbrodt and other clinicians prescribed heroic doses with the specific intent of changing the constituents of the blood. A third group of clinicians held that the remedial value of creosote occurred when it was excreted in considerable quantities by the lungs. When this happened, so argued this school of advocates, creosote destroyed the germs of phthisis.[13(343)]

Since creosote was eliminated principally by the kidneys and skin, it was considered to have a special value as a pulmonary antiseptic. "All the impure blood goes to the lungs to be purified before being circulated over the body,"wrote J.B. Wright in 1902. "The lungs are therefore more thoroughly saturated with creosote than any other one viscus of the body. The pulmonic circulation is small compared with the systematic circulation, and as the blood of the body is forced through it, the lungs are thoroughly bathed with this creosote-charged blood to a greater degree than any other viscus of the body." Accordingly, Wright believed in prescribing creosote in tuberculosis pulmonalis until the patient "is saturated with the drug." Typically he began with 15 drops and increased the dosage one drop each day until the patient was taking 40 to 50 drops three times each day. He continued this level of medication for a year or more after the patient was cured.[6(199-200)]

Although many physicians discovered that patients could not tolerate large doses of creosote, notable exceptions were reported in the medical journals. C.W. Graham, for example, commented in the *British Medical Journal* in 1898 that one of his patients with pulmonary tuberculosis began taking beechwood creosote and inhalations of guaiacol. He steadily increased the dosage until, at the the end of one month, the patient was taking 340 minims every 24 hours without any toxic effects. He continued prescribing this level for three months, then reduced the dosage to 140 minims daily. Believing that the value of creosote in the treatment of phthisis depended upon the patient's "exceptional tolerance," Graham insisted on carrying the dosage to the limits of a patient's endurance.[34]

Because of creosote's known toxicity, scientists sought a form of the drug that would permit its maximum dosage with a minimum danger to the body. Although they experimented with clysters, suppositories, hypodermic injections, capsules, and keratin-coated pills, the toxicity levels remained dangerously high. Finally, the chemist von Hayden combined the phenol group with the organic acids so that the corrosive toxicity of phenol was eliminated while its germicidal power remained as powerful as ever. With this new form available, doctors administered full doses of phenol carbonate or creosote carbonate without deleterious side-effects. Chaumier gave as much as 75 grains daily, reputedly with good results.[13(345)] In addition, large doses of phenol oleate or oleo-creosote, containing 33% pure creosote, yielded results without injury to the patient. With phenol oleate and carbonate distributed the entire length of the small intestine without the evils of accompanying toxicity, physicians had in their hands an ideal medicine for bacterial diseases.[33(431-2)]

Guaiacol, an important derivative obtained by the fractional distillation of beechwood creosote, was a colorless liquid which had an odor very similar to creosote. Max Schueller (1843-1907) of Berlin proposed it as a substitute for creosote in the treatment of consumption. Clinicians claimed that guaiacol formed compounds in the blood that aided in the elimination of the tubercle bacilli. The typical dose for a child consisted of one to three drops while, for adults, physicians prescribed three to five drops, four times each day, either in pill form or as a wine. Doctors also gave guaiacol by inhalation and subcutaneous injection. Carbonate of guaiacol, and other guaiacol compounds (biniodide, guaiacol benzosol, guaiacol salol, and guaiacol cinnamah or stryacol) were also tested in the treatment of consumption.[13(345-6)]

Physicians suspended creosote carbonate (Creostal) in wine, egg-emulsion, or cod-liver oil, or gave it hypodermically in its pure form for tuberculosis, chronic bronchitis, chronic intestinal catarrh, enteric fever, and certain cases of idiopathic anemia where phthisis seemed imminent. Physicians also prescribed creosote phosphite (Phosphatol), and guaiacol carbonate (Duotal), and guaiacol phosphite (Phospho-guaiacol) for phthisis; creosote valeriante (Eosote) for epidermic medication and gasteric fermentation; guaiacol valerianate (Greosote) for neuralgia, lupus, acne, and chilblains; sulphaminol-creosote and sulphaminol-guaiacol for the treatment of tuberculosis of the nose and larynx; and oleo-creosote for bronchitis and tuberculosis.[31(116)]

As late as 1900 researchers such as Frederick Cleveland Test, M.D., assistant professor of orthopedic surgery at Northwestern University Medical School, were lamenting the decline of older remedies such as creosote at the time when the materia medica was receiving so many additions in the form of synthetic coal-tar derivatives, recently identified alkaloids, new organic salts of the metals, and similar new drugs. Except for the treatment of tuberculosis and as the poor-man's relief of nausea and vomiting, creosote had lost much of its former glamor, and went into eclipse. Nevertheless, according to Test, the actual scope of creosote's value had become wider, as shown by the use of its derivative guaiacol in typhoid fever and in the treatment of pneumonia.[35(508-9)] To treat "fermentative intestinal disorders," Test considered creosote especially beneficial; when combined with a mild purgative to empty the alimentary tract, it rendered the canal free of gastrointestinal disturbances. Creosote's germicidal properties as well as its action on mucous membranes by stimulating the glands and exercising a sedative effect on the nerve endings afforded a wide field of usefulness. Small doses, frequently repeated, and thoroughly mixed with maltine or some other medium, rendered absorption more rapid and complete, and its value appreciated.[35(511)]

Despite its limited usage, physicians at the turn of the century were administering creosote internally by mouth and rectum, subcutaneously, externally, and by inhalation. J.A. Burnett, writing in the *California Eclectic Medical Journal* in 1913, remarked on the success of inhalation using three different mixtures: first, using phenol, oil of eucalyptus, and creosote; second, carbolic acid, creosote, tincture of iodine, and alcohol; and third, oil of pine needles, guaiacol, camphor, menthol, and oil of eucalyptus.[36] Of the different modes, internal administration remained the preferred choice of physicians. Wright warned that the subcutaneous method could not be continued for long because it produced a swollen, reddened area, which lasted for days and terminated in an induration of even longer period. Nevertheless, according to Wright, creosote had excellent antiseptic properties. "Creosote-charged blood," he wrote, "goes to every organ of the body, destroying germs or rendering the soil less fertile for them as it goes."[6(199)]

Military physicians in India prescribed creosote as an antipyrectic, rubbing about 10 minims into the abdomen and then covering the area with spongiopiline and a bandage. Edgar R. Parry, surgeon for the 42nd Gurka Rifles in Shillong, treated patients with lobar pneumonia and remittent fever with external applications of creosote over the abdomen to break the fever. This diaphoretic action, when first applied, brought a reduction in temperature for about 24 hours and, unlike the cold bath or wet pack and sponging, avoided the risk of chill.[37] As late as 1910, Major John E.B. Wells of the Royal Army Medical Corps noted creosote's usefulness in pneumonia and in influenza by means of an axillary inunction which produced sweating and lowered body temperature. He rubbed 10 minims of pure creosote gently into the right axilla and then dressed his patients in wool or flannel to encourage sweating.[38]

During their war with Russia in 1904-5, the Japanese Army employed creosote as a prophylactic against diseases "whose etilogy is the presence of specific pathogenic organisms in the digestive tract." The decision for this derived from investigations carried out before the war by Okada, a professor of hygiene at the Army Medical School at Tokyo, and his assistant Totsuka. They discovered that the bacillus E. coli, when treated with weak solutions of creosote, became inimical to other micro-organisms introduced into the digestive tract. Accordingly, the Japanese Army ordered creosote pills for its troops when they took to the field in 1904. Each soldier carried a tin box containing 90 pills, each pill containing 1.5 grains of creosote. Soldiers were instructed to take one pill with each meal, thus consuming a box of 90 pills each month. As a result of this campaign, cases of enteric fever among the Japanese troops stationed in Manchuria in 1904 and 1905 were comparatively few.[39]

Nevertheless, the results were not conclusive since Russian troops, who apparently had taken no such prophylactic, suffered no greater incidence from the disease than did the Japanese. In addition, information received from medical missionaries of the Scotch Presbyterian Mission in Manchuria suggested that the percentage of enteric incidence had been roughly the same among soldiers in both armies.[39]

Into the early decades of the 20th century, creosote remained a popular favorite. Some physicians noted that the drug was the best solution in which to soak false teeth overnight. Others saw it as a "splendid local antiseptic" which they diluted and injected into carbuncles and abscesses. Still others recommended it as an appetizer which aided digestion by cleaning the stomach and exciting gastric secretion. According to Hughes, editor of the *Alienist and Neurologist,* creosote was the best antiseptic available on the market, especially for its "anti-auto-infection properties." He prescribed it mixed with glycerine and water as a morning and nighttime gargle and mouthwash.[28(406)] Finally, there were those who continued to rely on creosote as the best remedy for constipation, prescribing it in dosages of up to 8 minims, in hypodermic injections, and by rectum.[31(115),40(222)]

Today, wood creosote (beechwood) continues to be used as an antiseptic and as an expectorant; however, the hope that it would act as a systemic antibacterial agent has since been abandoned. As a gastrointestinal antiseptic, creosote is used in the treatment of fermentative gastritis and enteritis and as a local anesthetic upon the gastric mucosa in nausea and vomiting. For internal use, pharmacists and manufacturers typically have mixed it with ipecac, menthol, licorice, or wild cherry. Externally, physicians continue to use creosote as a surgical disinfectant and in various skin diseases, both for its local anesthetic and antibacterial properties. And in dentistry, creosote is sometimes employed for obtunding sensitive dentine and as an ingredient of pastes for destruction of nerves.

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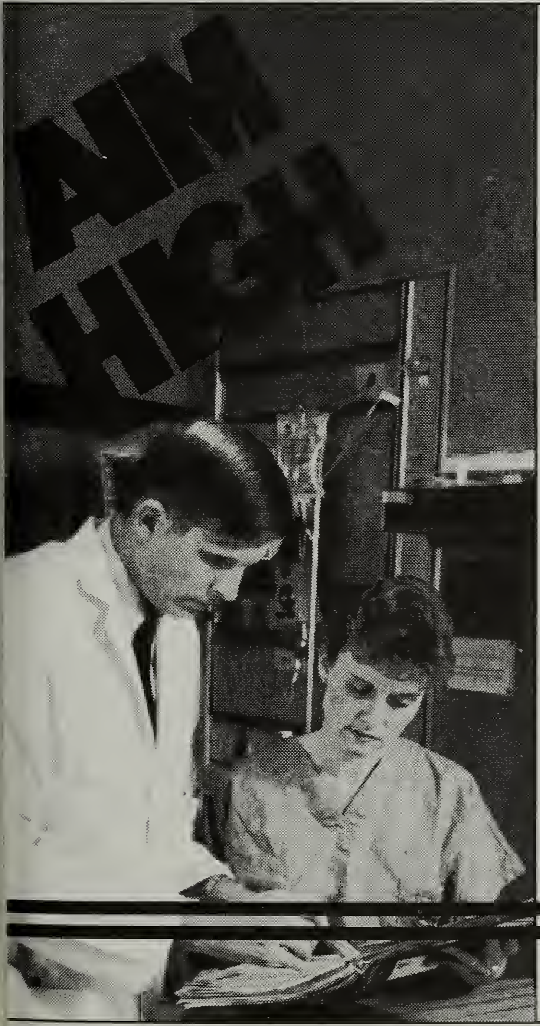

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Variations in Coding Practices Among Connecticut Urologists for the Medicare Population

PETER C. ALBERTSEN, M.D. AND EDWARD A. KAMENS, M.D.

ABSTRACT—As health care costs continue to rise, alternatives to the traditional fee for service system of physician reimbursement are being explored. Recently a resource-based relative-value system was enacted by Congress to correct some of the perceived inequities of Medicare reimbursement. Since reimbursement for evaluation and management services, also known as cognitive services, are based on Current Procedural Terminology (CPT-4) codes, we reviewed Medicare claims data for fiscal year 1986-87 to identify the coding habits of Connecticut urologists.

We found that Connecticut urologists file 99% of their claims for cognitive services in one of six categories. Furthermore, we found that within these broad categories an average of 82% of the claims were filed under one primary practice specific code. The particular code selected, however, varied markedly between practices. Our data suggest that Connecticut urologists have adopted different standards for using CPT-4 codes and have adjusted for these differences through their fee schedules. These findings highlight the need for increased precision in CPT code definitions for cognitive services before they can be adapted to a reimbursement system based upon relative-value scales.

Introduction

As medical expenditures continue to soar uncontrollably, government and private payers have taken greater interest in alternatives to the traditional system of physician reimbursement based upon usual, customary, and reasonable fee schedules.[1,2] Congress has recently adopted the "resource-based relative-value scale" (RBRVS) developed by Hsaio et al, whereby medical services provided by physicians are assigned a score based on the relative input of total work, practice costs, and the cost of specialty training.[3] Physician reimbursement is linked to the RBRVS scores and will be adjusted annually by Medicare. Unfortunately, earlier studies of evaluation and management services, also known as cognitive services, have shown large systematic differences in the way physicians in different specialities understand and use the coding system.[4]

To further our understanding of coding habits among Connecticut urologists, we reviewed Medicare claims data for fiscal year 1986-87. Our analysis focused on the variations between different practice groups in their selection of CPT codes describing cognitive services. Specifically we hoped to determine whether urologists throughout the state used similar standards for classifying cognitive services. We also reviewed the charges associated with each of the commonly used CPT codes to determine the extent of variation throughout the state. This kind of information is essential to understanding the financial impact of implementing a resource-based relative-value system.

Material and Methods

Practice specific summary claims data for urologists practicing within Connecticut were reviewed for fiscal year 1 July 1986 - 30 June 1987. All claims were originally filed using current procedural terminology (CPT) coding. Data analysis included all claims filed for cognitive services (90000 codes).

Seventy-two urologic practices representing 97 urologists were identified and included within the study. Data from urologists practicing within multispecialty groups were unavailable, but this would represent only a small fraction (<5%) of the urological care provided in the state.

Initial review of the data demonstrated that 99% of the claims fell into one of three types: office visits, hospital visits, and consultations. These groups in turn could be subdivided into two groupings based upon whether the service was provided to a "new" or "established" patient. These six categories formed the basis for subsequent data analysis.

Claims were first counted by practice to determine the variations in distribution between each of these six catego-

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ries. Next each category was reviewed separately to determine whether a primary CPT code could be identified. For new patient office visits, for example, five CPT codes ranging from "brief" to "comprehensive" are available. Most Connecticut urologists select one of these codes for over 50% of the claims they file. The claims filed by each practice were reviewed to determine which of the CPT-4 codes was the practice-specific primary code for each of the six study catagories. If no code accounted for more than 50% of the claims in the category, the average of the two codes most frequently used was selected.

Similarly, the charges associated with each of the six primary billing codes were determined for the 72 urologic practices studied. The charges associated with the two most frequently occurring codes were averaged when a single primary code could not be identified.

Results

A total of 59,956 claims for cognitive services were filed by 72 urologic practices during fiscal year 1986-87. Office visits accounted for 38,166 claims, hospital visits for 13,900 claims, consultations for 7,238 claims. Nursing home and home visits accounted for the remaining 652 claims and represented less than 1% of the total. Office, hospital, and consultation services were further separated according to whether services were provided either to new or established patients. These totals are listed in Table 1.

Primary practice specific billing codes could easily be identified in virtually all of the 72 urologic practices reviewed. In each of the six categories studied an average of 82% of the claims were filed under the practice-specific primary code for that category (Table 1).

The number of urologic practices using each of the different CPT codes as their primary code is listed in Table 2. In some instances the totals do not sum to 72 since not all urologic practices file claims in each category. Forty-nine practices, for example, filed no claims for consultation services provided to established patients during fiscal year 1986-87.

Table 3 shows the average and range of percentages of the claims filed for each of the six categories studied. The typical practice coded 13% of all claims filed as new patient office visits. This number ranged from a low of 0% to a high of 75%. Similar figures are noted for the other five categories.

Charges associated with each of the primary billing codes for each urologic practice are plotted in Figures 1-3. No statistically significant differences were noted in the range of charges received for services provided under the different CPT intensity levels. This was true for each of the six categories studied.

Discussion

As health care costs continue to escalate, government and industry have aggressively sought innovative methods for reimbursing physicians for the services they render. Recently Hsaio et al published a long-awaited study that attempted to quantify physician efforts in terms of the relative inputs of total work, practice costs, and the cost of specialty training.[3] In a companion article Braun et al reviewed evaluation and management services, also known as cognitive services, to determine whether a consensus existed within and between specialties concerning estimates of the magnitude of work associated with particular cognitive services.[4] They found that physicians agree closely in their ratings of various cognitive services. Furthermore they found that work estimates for cognitive services correlated closely with the time expended. Unfortunately they also identified wide variations in the coding and billing practices within and among different specialties.

We reviewed the coding and billing practices of Connecticut urologists to determine the extent of variation within a single specialty. Interestingly we found that Connecticut urologists were internally very consistent in their coding habits. Almostly uniformally urologists selected a single primary code for the majority of claims filed under each of the six categories studied. With only two exceptions, however, every possible CPT-4 code was selected as a primary billing code by at least two or more practices.

Braun et al have shown that the work input for cognitive services correlates closely with the amount of time expended with the patient. In their recent report they used several clinical vignettes to quantitate the work and time input associated with various CPT codes. Among the urologists interviewed, for example, a new patient office visit coded 90017 (extended visit) was found to entail a mean time expenditure of 28 minutes and translate into 94 work units. Similarly, a new patient office visit coded 90020 (comprehensive visit) was found to involve a mean time of 38 minutes or 141 work units. These results imply that the higher intensity codes involve more effort and justify greater reimbursement.

Our findings suggest that urologic practices within Connecticut either do not use time or effort as criteria for selecting CPT-4 codes or have adopted different standards throughout the state for translating work effort into codes. Between 77% and 93% of the claims filed by Connecticut urologists are filed under the practice specific primary code for that category. This implies that the majority of cognitive encounters in a typical practice involve the same level of work. Since different practices have selected different codes as their primary billing code, this implies that Connecticut urologists either practice on very different patient populations or what is more likely, have very different perceptions of the relative value of work that is associated with the different CPT-4 codes.

Another interesting finding is the wide variation in the distribution of claims within the six study categories. The average practice codes 13% of the Medicare claims as a new patient office visit. The range, however, extends from 0% to 75%. Presumably no new patients are seen in some practices, while in other practices three-quarters of the patients are "new." Similar results are seen for hospital visits. The average Connecticut urologic practice files 16% of its Medicare claims as hospital visits for established patients. Some practices, however, appear to see no patients in the hospital, while in other practices hospital patients constitute almost half of the claims for cognitive services.

Although these findings might suggest that urologists practice in very different environments, a more likely explanation is a recording bias resulting from the imprecise definitions associated with CPT-4 codes. What differentiates a "new" patient visit from an "established" patient visit? Should the patient be new to the practice, not have been seen for several years, or does a "new" patient visit simply imply a new episode of care? Are similar criteria being used throughout the state to define consultations, hospital visits, and office visits?

Indirect evidence from physician charges supports the concept that imprecise definitions result in significant variations in charges associated with particular codes. Figures 1-3 correlate physician charges with the primary coding choice for that practice. The plots show no significant differences in physician charges based on coding intensity for any of the six categories studied. Urologists who routinely code on the lower end of the intensity scale charge the same range of fees as their colleagues who select higher coding values. Different practices appear to employ different standards when selecting codes, but variations in fee schedules seem to partially correct for these differences.

As suggested by Braun et al, further work is needed on the RBRVS system for cognitive services, especially now that it has been implemented by congress as the basis for a fee schedule. The Physician Payment Review Committee in their second annual report noted that "to account for differences in work by specialty for visits and consultations, definitions of existing codes could be improved and their use standardized, or a new set of codes might be developed."[5] If the current CPT-4 system is to be used, physicians must be given an opportunity to readjust their fee schedules to comply with national or regional standards. Braun et al have noted that the intensity of evaluation and management services correlate closely with the time expended and suggest that future CPT codes incorporate time factors in their definitions.[4] While this is one potential solution, it possibly penalizes more efficient providers.

As our health care system continues to mature and evolve, increasing effort is being placed on designing an equitable system of physician reimbursement. The recently enacted resource-based relative-value system attempts to address problems of physician reimbursement, but based upon our data it cannot be equitably implemented using the current CPT-4 system. As in other areas of our health care system, cross subsidies and ambiguous coding practices are no longer acceptable to the payers of health care services. Therefore, urologists and all Connecticut physicians must take an active interest in quantifying and defining what they do for patients if they wish to continue to influence the development of new reimbursement systems.

Table 1
Medicare Claims Filed by Connecticut Urologists
Cognitive Services Fiscal Year 1986-87

Type of Cognitive Claim		*Total Number of Claims Filed*	*Number of Claims Filed Primary Code*	*Percent of Claims Filed Primary Code*
Office visit -	New	6,230	5,173	83%
	Established	31,936	25,621	80%
Hospital visit-	New	3,664	3,280	90%
	Established	10,236	8,677	85%
Consult -	New	6,451	4,970	77%
	Established	787	731	93%

Table 2
Coding Practices of Connecticut Urologists 1986-87
Primary Coding Choice for Each of 72 Urologic Practices

Intensity of Service	*Office*		*Hospital*		*Consult*	
	New	*Estab*	*New*	*Estab*	*New*	*Estab*
Minimal	*	0	*	*	*	*
Brief	0	14	8	21	*	*
Limited	11	21	*	20	9	5
Intermediate	17	23	27	18	12	*
Extended	21	11	*	8	13	4
Comprehensive	21	3	34	2	35	11
Complex	*	*	*	*	3	3
Total	70	72	69	69	72	23

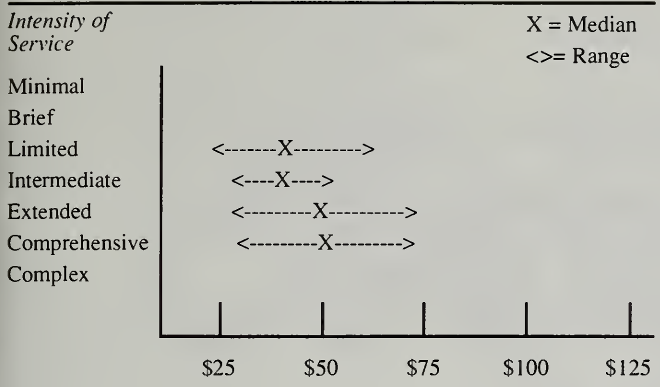
*Current Procedural Terminology does not provide for coding under this level of service.

Table 3
Distribution of Claims Within an Average Urologic Practice

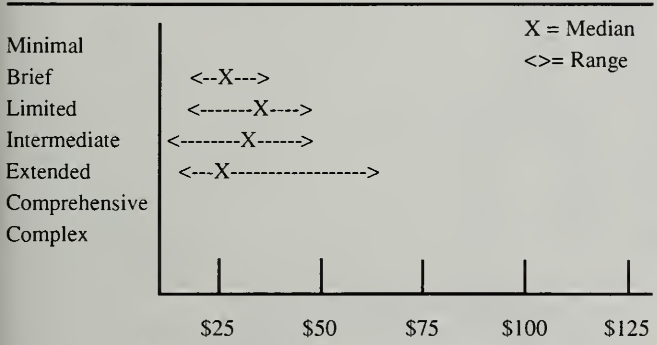
	Office	*Hospital*	*Consult*
New Patient	13% (range 0-75%)	6% (range 0-21%)	11% (range 1-40%)
Established Patient	53% (range 1-91%)	16% (range 0-44%)	1% (range 0-4%)

Figure 1

Office Visit - New Patient



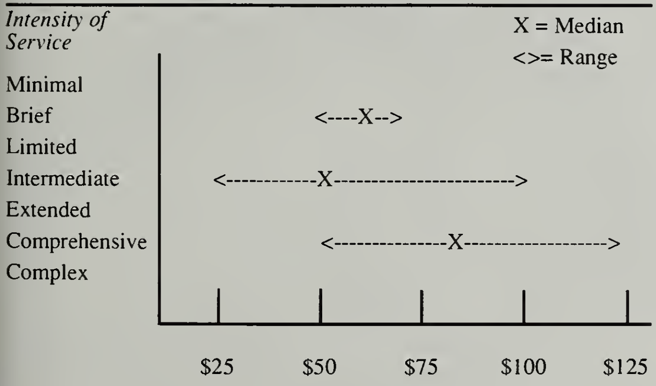
Office Visit - Established Patient



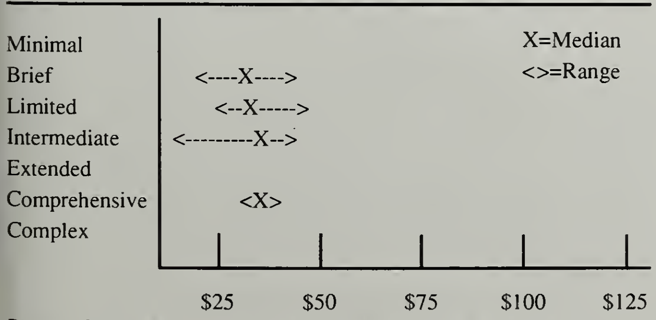
Range of Charges for Cognitive Services Using Practice Specific Primary Coding Choice

Figure 2

Hospital Visit - New Patient



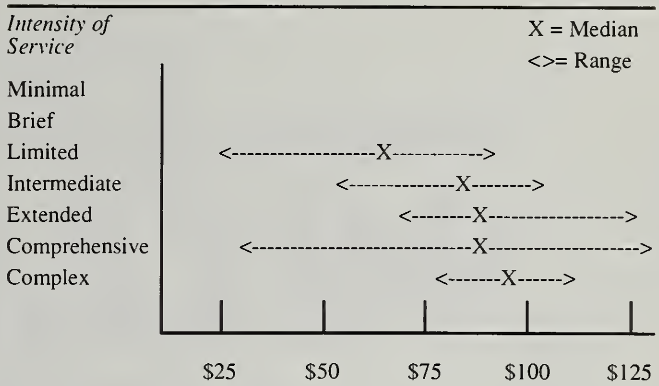
Hospital Visit - Established Patient



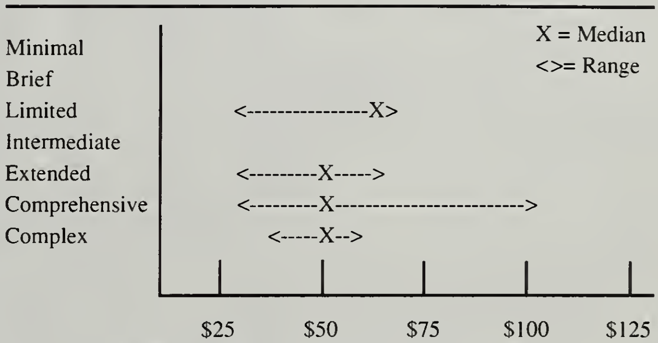
Range of Charges for Cognitive Services Using Practice Specific Primary Coding Choice

Figure 3

Consult - New Patient



Consult - Established Patient



Range of Charges for Cognitive Services Using Practice Specific Primary Coding Choice

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The Treatment of Sleep Disorders of Older People

NATIONAL INSTITUTES OF HEALTH

Introduction

THE increase in the number of people over 65 and the rise in the proportion of older people represent a marked change in the demographic patterns in this country that will have profound social, economic, medical, and personal consequences. Individuals over 65 constituted 4% of the American population in 1900 and nearly 10% in 1972. By the year 2000, it is estimated that they will comprise over 13% of the population and by 2050 will represent more than 21% of Americans.

A large proportion of older people are at risk for disturbances of sleep that may be caused by many factors such as retirement and changes in social patterns, death of spouse and close friends, increased use of medications, concurrent diseases, and changes in circadian rhythms. While changes in sleep patterns have been viewed as part of the normal aging process, new information indicates that many of these disturbances may be related to pathological processes that are associated with aging.

Although the exact numbers are not yet known, it has been estimated that disturbances of sleep afflict more than half of the people 65 and older who live at home and about two-thirds of those who live in long-term care facilities. Problems in sleep and daytime wakefulness disrupt not only the lives of older persons but also those of their families and caregivers. People over 65 years of age now constitute almost 13% of the American population but consume over 30% of all dispensed prescription drugs, as well as an unknown percentage of over-the-counter medicines. A large proportion of these drugs are sedatives and hypnotic agents, the safety and efficacy of which have not been established for older people. Nor has it been established to what extent drugs contribute to or alleviate problems of sleep. It is necessary to understand the causes of these disorders and to develop better treatment strategies, including nonpharmacological methods.

In addition to affecting the quality of life, troubled sleep has been implicated with excess mortality. Controversy also exists concerning the causes, diagnosis, assessment, and specific treatments of sleep disorders in older people.

In an effort to assess the current state of knowledge and determine what changes in sleep are clinically important, how sleep disorders are best diagnosed and treated, and how the public can establish good sleep practices, the National Institute on Aging, the Office of Medical Applications of Research, the National Institute of Neurological Disorders and Stroke, the National Heart, Lung, and Blood Institute of the National Institutes of Health, and the National Institute of Mental Health, convened this conference. Following one and one-half days of presentations by experts in the relevant fields, a consensus panel consisting of representatives from neurology, psychiatry, internal medicine, geriatric medicine, pulmonology, otolaryngology—head and neck surgery, epidemiology, biostatistics, pharmacology, and the public considered evidence and formulated a consensus statement responding to these key questions:

1. What are the changes in sleep and wakefulness as functions of aging and of diseases of older people?

NIH Consensus Development Conferences are convened to evaluate available scientific information and to resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public

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Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus, and at 50 mg/kg, it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Studies in lactating women have shown that 0.1% of an oral dose is secreted in human milk in proportion to plasma concentrations. Because of growth depression in pups reared by treated lactating rats, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Healing rates in elderly patients were similar to those in younger age groups as were the rates of adverse events and laboratory test abnormalities. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of varying durations included almost 5,000 patients. Among the more common adverse events in domestic placebo-controlled trials of over 1,900 nizatidine patients and over 1,300 on placebo, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common with nizatidine. It was not possible to determine whether a variety of less common events was due to the drug.

Hepatic—Hepatocellular injury (elevated liver enzyme tests or alkaline phosphatase) possibly or probably related to nizatidine occurred in some patients. In some cases, there was marked elevation (>500 IU/L) in SGOT or SGPT and, in a single instance, SGPT was >2,000 IU/L. The incidence of elevated liver enzymes overall and elevations of up to three times the upper limit of normal, however, did not significantly differ from that in placebo patients. Hepatitis and jaundice have been reported. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

CNS—Rare cases of reversible mental confusion have been reported.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to nizatidine. Impotence and decreased libido were reported with equal frequency by patients on nizatidine and those on placebo. Gynecomastia has been reported rarely.

Hematologic—Fatal thrombocytopenia was reported in a patient treated with nizatidine and another H_2-receptor antagonist. This patient had previously experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

Hypersensitivity—As with other H_2-receptor antagonists, rare cases of anaphylaxis following nizatidine administration have been reported. Because cross-sensitivity among this class has been observed, H_2-receptor antagonists should not be administered to those with a history of hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever, and nausea related to nizatidine have been reported.

Overdosage: Overdoses of Axid have been reported rarely. If overdosage occurs, activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

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What are the diagnostic criteria that establish clinical abnormalities? Which are clinically and epidemiologically important?

2. What are the indications for a diagnostic evaluation? What sequence of assessment methods should be used to determine if the diagnostic criteria are met?
3. What are the indications for the treatment of sleep disorders?
4. What are the common medical practices and lay treatment practices and their health implications?
5. What should the medical profession and general public know about good sleep hygiene and treatment of sleep disorders, and what should be done to increase awareness?
6. What are the directions for future research?

1. What Are the Changes in Sleep and Wakefulness as Functions of Aging and of Diseases of Older People? What Are the Diagnostic Criteria that Establish Clinical Abnormalities? Which Are Clinically and Epidemiologically Important?

Sleep is a distinctive and essential component of human behavior. Nearly a third of the life of a normal adult is spent sleeping. Sleep is divided into rapid eye movement (REM) and non-REM sleep. REM sleep is characterized by a low amplitude pattern in the EEG, an associated loss of muscle tone, and the presence of rapid eye movements. Non-REM sleep is characterized by sleep spindles and slow wave activity in the EEG. Sleep is differentially distributed into the dark portion of the daily cycle of light and dark. This regulation of sleep reflects basic brain mechanisms that provide the circadian organization of both behavioral and physiological processes.

During aging there are typical changes in the pattern of sleep. The amount of time spent in deeper levels of sleep diminishes. There is an associated increase in awakenings during sleep and in the total amount of time spent awake during the night. In part, these changes appear to represent a loss of effective circadian regulation of sleep.

In carefully screened, medically healthy, older subjects, there are relatively few individuals who have symptoms related to these changes in sleep and in the distribution of sleep and waking behaviors. Many older individuals, however, suffer from a variety of medical and psychosocial problems and these are very often associated with disturbances of sleep. These include psychiatric illnesses, particularly depression; Alzheimer's disease and other neurodegenerative diseases; cardiovascular disease; upper airway incompetence; pulmonary disease; arthritis; pain syndromes; prostatic disease; endocrinopathies; and other illnesses.

The diagnostic categories that establish clinical abnormalities of sleep arise from two sets of data. The first is derived from evaluation of the patient's history which is classified into syndromes as have been described in the *International Classification of Sleep Disorders.* None of the disorders are specific for older people, but nearly all occur in this population. The second set comes from electrophysiological studies. Both provide valuable information, but each has its own limitations.

There is little agreement among workers in the field about what is clinically normal and what is clinically abnormal, except in extreme cases (for example, high values of indices of sleep disordered breathing). Also, measurements are not obtained in a standardized way. Much needs to be learned, and an important first step is to decide upon a standardized approach to data collection. The new classification scheme is an important first step in the standardization process.

In the assessment of the behavioral aspects of sleep, standardization is needed before epidemiological subpopulations can be defined and surveyed. The validity (including face validity) and reliability of standardized instruments and settings must be determined before sensitivity, specificity, and prevalence are assessed. Additional considerations are cost and ease of measurement. With standardized, agreed-upon instruments intra- and intersubject variability can be measured and linked with other clinical observations.

Standardized approaches to data collection for both the clinician and the researcher are particularly important in the measurement of variations over time. In many situations clinical action is based on an inference that the patient's condition has changed. If this judgment is guided by a psychometric instrument, then the reliability of the estimated change, in the presence of intrasubject variability, must be established.

The rapid and thorough evaluation of new and existing technology will aid in the development of standardized approaches to data collection. The evaluation begins with the specification of the clinical need. Comparisons with competing technology must be made as objectively as possible, and the ideal research design for accomplishing this is the randomized double blind clinical trial.

It is difficult to answer questions about changes in sleep and wakefulness as functions of aging or of disease in older people because basic epidemiologic descriptive studies have not yet been carried out. Studies of the distribution of sleeping patterns and "disorders" need to be conducted in the "community" utilizing a representative sampling scheme so that the relationship of sleep patterns to possibly pertinent cultural, demographic, and other variables can be explored.

There is a need for epidemiological studies of sleep disorders: international and cross-cultural comparisons and case-control studies may confirm and generate etiological hypotheses. The natural history of certain sleep disorders is not well described: Do they spontaneously remit? What is the relationship to cardiovascular disease and life expectancy? Cohort studies may help advance our understanding of the natural history of these disorders.

Similarly, it is difficult to determine which diagnostic criteria are important in establishing clinical abnormalities. The field of sleep disorder research has largely approached this problem by attempting to separate "normal" from "abnormal" or "diseased." However, population distributions of the phenomena employed as diagnostic criteria (eg, periodic movements in sleep or apneic episodes) are not well described. Current threshold values are usually not validated; and test characteristics (sensitivity, specificity, predictive values) are largely unavailable. Furthermore, inter- and intraobserver variation in test interpretation has been rarely studied.

While the severe forms of clinical entities, such as sleep apnea, are generally accepted and criteria agreed upon, mild and moderate forms are not well distinguished. Study of the distribution of these phenomena in populations, linking them to clinical outcomes, is lacking. For example, persons with a mild degree of periodic movements in sleep or apnea may be asymptomatic and not suffer any appreciable morbidity. It will be difficult to establish diagnostic criteria if the frequency of these events is not linked to natural history studies and eventual health outcomes and functional impairment.

2. What Are the Indications for a Diagnostic Evaluation? What Sequence of Assessment Methods Should Be Used to Determine if the Diagnostic Criteria Are Met?

Diagnostic evaluation begins with the recognition of a potential disorder by patient history or physician suspicion. Screening questions should include: 1) patient satisfaction with his or her sleep; 2) intrusion of sleep or fatigue into daily activities; and 3) complaint by bed partner or other observers of unusual behavior during sleep. A positive response to these questions should trigger a more detailed history of the onset, severity, duration, and pattern of the complaint, and lead to a differential diagnosis.

Three major types of sleep complaints are excessive sleepiness (hypersomnia), difficulty in initiating or maintaining sleep (insomnia), and strange or unusual behavior during sleep (parasomnias).

A careful medical history is needed to determine the presence and severity of concomitant disease. The history of snoring, breathing pauses, or periodic movements during sleep is sometimes better described by the bed-partner or other observers. Prescribed medications, especially sedatives; alcohol use; and self-medication can have a significant effect on sleep and may impair cardiopulmonary mechanisms during sleep. Psychiatric history and evaluation identify anxiety, depression, or major life events which are known to affect sleep habits or hygiene. In some cases the use of a patient sleep log to evaluate sleep/wakefulness patterns will serve to identify rhythmic or circadian disturbances or to document the magnitude of sleep intrusion into daily activities. Appropriate physical examination will depend upon the nature of the complaint and history elicited from the patient. For example, heavy snoring may necessitate a detailed examination of the nose and throat. Appropriate laboratory test may be similarly indicated.

Given additional training and education, primary care physicians should be capable of initial assessment and management of the majority of sleep disorders presenting in the older population. When necessary, referrals should be made to individuals or a center with recognized skills in the indications for and application of more specialized tools, such as polysomnography or multiple sleep latency tests for diagnosis and recommendations for therapy.

Polysomnography is indicated when a sleep related breathing disorder is suspected and may be useful for certain behavior or movement disorders during sleep. Polysomnography followed by a multiple sleep latency test is useful for establishing the diagnosis of narcolepsy and for quantitating daytime sleepiness. At present, there are insufficient data to assess the value of polysomnography in the routine evaluation of insomnia, depression, or dementia.

Limited monitoring on an ambulatory basis may be useful to assess efficacy of therapy for sleep apnea. Technologic advances, standardization of variables, and cost-effectiveness need to be addressed before incorporating ambulatory monitors into epidemiologic studies or the clinical practice of sleep disorders medicine.

3. What Are the Indications for the Treatment of Sleep Disorders?

The goals of therapy of sleep disorders can be classified as:

a. Reducing morbidity;

b. Reducing excess mortality; and

c. Improving quality of life for patient and family.

Sleep disorders have been classified extensively. The major focus of this conference could, however, be summarized as dealing with two primary types of complaints or disorders, for which there is evidence to suggest that treatment is beneficial. These consist of:

a. The hypersomnias, primarily represented by obstructive sleep apnea; and

b. The insomnia complaints, which can be due to a variety of psychiatric and medical disorders.

Indications for Treatment of Obstructive Sleep Apnea

Obstructive sleep apnea is a potentially reversible cause of daytime hypersomnia, which may be associated with comorbid conditions and even excess mortality. Effective treatment is available for many patients. Development of better and more effective treatment strategies should, however, be encouraged.

Treatment is recommended for more severe degrees of this disorder. Objective indices of severity elicited by polysomnography should include a high index of respiratory disturbances per hour, repetitive episodes of hypoxemia, and an abnormally shortened sleep latency. Strict guidelines for therapy have not been adequately validated to dictate thresholds for distinguishing less severely affected patients. At the present time, considerable reliance is made on clinical judgment to initiate a therapeutic trial or regimen.

Indications for Treatment of Insomnia Complaints

Complaints of insomnia are very common in the older patient. Insomnia is a symptomatic expression of a constellation of medical conditions that are not entirely related one to another. Insomnia may be psychiatric (eg, depression, anxiety), physiological (eg, central apnea, limb movement), pharmacological (eg, prescribed or unprescribed drugs or alcohol), or of medical origin. It may coexist with other sleep disorders (such as apnea), but this may be merely coincidental.

Since insomnia has many causes, the indications for treatment are dependent on the etiology. A thorough medical evaluation is essential prior to initiating treatment. Indications for therapy will be driven by the underlying cause and severity of symptoms.

Attention was given to periodic movements in sleep which appear to be very common in the older patient. Certain pharmacological treatments appear to be effective in patients who find this condition distressing. There is, however, insufficient evidence at this time to indicate whether or not the disease state or its treatment affect morbidity in the older patient. Moreover, the long-term benefits and risks of treatment of periodic movements in sleep are unknown, and, therefore, further investigations are recommended.

Insomnia may also be related to circadian rhythm disorders. Amplitude and phase relationships are often altered in the older person. These changes may produce a variety of somatic complaints and sleep disturbances. Such alterations occur during shift work, transmeridian travel, or changes in daily routine or sleep patterns (earlier arousal and earlier bedtime tendency), or they may occur spontaneously.

Therapy should be directed toward appropriate control of the environment and adequate counseling of the patient and the employer. It may include appropriately timed bright light exposure.

Insomnia resulting from medical or psychiatric causes should be managed primarily by appropriate treatment of the underlying condition.

4. What Are the Common Medical Practices and Lay Treatment Practices and Their Health Implications?

Insomnia

Although hypnotic medication is frequently prescribed by physicians for insomnia and secured either across the counter or "extralegally," hypnotic medication should not be the mainstay of management for most of the causes of disturbed sleep.

Since a large proportion of individuals with chronic insomnia have psychiatric complaints, particularly depression, but also anxiety, panic states, alcoholism, and others, treatment should be directed toward the underlying disorder. In the case of depression the tricyclic antidepressants are frequently useful in the absence of contraindications. One can take advantage of the sedative effect of some of these agents in addition to their more specific effect on the depression. Some agents may actually cause sleeplessness and should be used in the morning.

Other diseases and conditions which cause or contribute to insomnia, such as congestive heart failure, hyperthyroidism, pulmonary disease, esophageal reflux, and arthritis, should be treated specifically with the reminder that medications such as steroids and theophylline may cause sleep disturbance, as can the timing of administration of diuretics.

Pharmacologic therapy may be helpful if it is determined that periodic movements in sleep are contributing to insomnia and require treatment. The long-term benefits of treatment have yet to be determined.

Other general measures such as sleep hygiene can be used as adjuncts to treatment of the specific causes of insomnia and tried when the cause is not clear or is unspecified. Sleep hygiene measures include regularization of bedtime (generally later rather than earlier); the use of the bedroom primarily for sleeping and sexual activity; exercise; avoidance of alcohol and caffeine; reduced evening fluid intake; and in the case of esophageal reflux, elevation of the head of the bed.

Short-term intermittent use of hypnotics and sedative tricyclics may be useful for temporary problems such as bereavement, dislocation, and situational anxiety. There are no studies which demonstrate their long-term effectiveness. Given the changes in drug metabolism associated with increasing age, all medication should be used with caution, especially those with long half-lives. Older people should avoid over-the-counter sleep medication due to their anticholinergic effects and questionable efficacy. L-Tryptophan (another commonly used over-the-counter-sleep-inducing agent) has been associated with eosinophilic myalgia syndrome and has been withdrawn from the market.

The role of pharmacological, behavioral, and phototherapeutic management of disorders of circadian rhythm regulation is currently under investigation.

Hypersomnia

When treatment is indicated for hypersomnia due to obstructive sleep apnea, certain general measures, if successfully initiated, may suffice. These include weight loss; avoidance of alcohol, sedatives, and hypnotics; the avoidance of the supine sleeping position; and management of nasal and nasopharyngeal disease.

The mainstay of treatment is the use of nasal continuous positive airway pressure (CPAP) which is frequently successful. It and other devices (including tongue retaining and jaw advancing appliances and cervical collars) need further study.

Where other measures, including nasal CPAP, fail or are unacceptable, surgical procedures may become an appropriate alternative treatment. Uvulopalatopharyngoplasty has been reported to be successful. There is evidence that the procedure may have better success when tailored to a demonstrated site of obstruction. Tracheostomy may be required if other procedures are unacceptable or fail.

In all therapeutic interventions there should be long term outcome assessment.

5. What Should the Medical Profession and General Public Know About Good Sleep Hygiene and Treatment of Sleep Disorders, and What Should Be Done to Increase Awareness?

The answer to this question involves defining the target audience, determining what information should be conveyed, and deciding how best to transmit the information.

Physicians and medical students, nurses, social workers and counselors, rehabilitation and respiratory therapists, discharge planners, and pharmacists and other allied health professionals are the groups to be approached first. We anticipate particular interest from providers of services to the older people including area agencies on aging, senior centers, and nursing homes.

Other special groups that are affected by sleep disorder issues include employers, pharmaceutical companies, members of the legal profession, and developers of technology. Funders of research, both public and private, must be involved in this developing field. Education also must be directed toward decision makers at local, state and national levels, including regulatory and legislative groups. There are also key decision makers in the private sector such as those in the insurance industry and health care systems.

Educational efforts must include the very groups we wish to help: the older persons, their families, and caregivers.

The information to be conveyed will differ in content, style, and depth depending on the audience—professionals, patients, and media. A particular educational emphasis is desirable for new physicians and researchers, even while it is recognized that there are many unanswered questions. Nevertheless there are general concepts that could be useful for all groups. The content should include concepts of sleep physiology and pathophysiology, and assessment and differential diagnosis.

Discussion of treatment approaches including technological devices, drugs, and life-style should address disadvantages as well as advantages. For audiences unfamiliar with the issue of sleep and the older person, the magnitude of the personal and societal toll in accidents, health, and unhappiness must be conveyed. Other key points include proper use of medications, preventive health measures, and good sleep hygiene practices. Individuals may satisfactorily cope with insomnia, and it may be transient. On the other hand, persistent insomnia may reflect major disease, and competent clinical consultation may be desirable.

Imagination and sustained effort are at the heart of the many educational efforts. For health professionals one goal is to include information on sleep in the curriculum of schools—not an easy task. More standard educational efforts include appropriate lay and professional publications, professional conferences, and continuing education. Lay or advocacy groups can contribute to the total educational effort, as well as benefit from it. Reaching the public can be facilitated by utilizing existing networks, for example, state and area agencies on aging, coordinated through the Administration on Aging. There are opportunities for communicating information in newsletters published by churches, hospitals, and senior centers. There is particular need to involve citizen groups who direct their efforts toward the older person. All media groups should be encouraged to discuss these issues.

The Public Health Service must take a more active role in educating and disseminating information to the public. Without such effort, this consensus report may not receive the wide dissemination which it deserves.

6. What Are the Directions for Future Research?

The conference presentations emphasized the problem of sleep disorders in older age due to the demographic shift in the American population to an increasing proportion in the over-65 age group, and to the public awareness of the interest of the medical community in diagnosis and treatment of these disorders.

The study of sleep and sleep disorders has advanced rapidly in the past 30 years. This advance has been most prominent in studies of normal sleep throughout the life span. However, the classification, diagnostic criteria, understanding of the basic mechanisms, natural history, and the efficacy of treatment in sleep disorders are still in early stages so that further research in all these areas is necessary. This is particularly true for the older population in whom these conditions may be more frequent and disruptive.

It is always difficult to define classification and diagnostic criteria in a relatively new area where clinical descriptions and observations predominate and where the interpretation of objective measures, even with existing and new technology, is hampered. Certainly, large studies of control populations with proper sampling methods are necessary. This is particularly the situation in older populations where controls without confounding disease are more difficult to obtain.

It is often necessary in alleviating illness to press forward with clinical descriptions and treatment even without knowledge of the basic mechanisms. However, it is only with elucidation of these mechanisms that rational approaches to therapy can be effected. The study of these disorders in older patients, who often have other diseases, affords some unusal opportunities. For example, how does the dopamine depletion in Parkinson's disease patients affect sleep architecture and cardiopulmonary adaptation? Also, older patients may take one or more drugs for other conditions, and this may afford an opportunity for clinical observations.

There have been extensive studies of sleep mechanisms in experimental animals. Efforts should be made to identify appropriate animal models for sleep disorders. Now it is possible to study old animals, including primates, and these studies should provide insight into the basic mechanisms of sleep changes in aging. The new interest in disordered circadian rhythms as a clinical observation opens up new areas of research.

Modern research techniques used in selected human cases might help identify biological markers for some of these disorders. Opportunities for clinical and pathological correlation should be encouraged. The application or development of new research techniques should provide added understanding of the neurobiology of sleep and its disorders.

The natural history of many sleep disorders has not been well described. Longitudinal studies into older age would clarify the progress of these disorders and their effect on morbidity and mortality. This is also necessary if one is to judge the efficacy of various treatment modalities. Important questions that can only be answered by long-term studies are whether some of the variations noted in the older population are the result of aging or of concomitant disease; whether these variations need to be tested further; and whether these variations are responsible for other medical conditions. This latter point needs clarification because of the questions regarding sleep apnea with oxygen desaturation and various forms of dementia.

An important area of study is the disruption of normal circadian rhythms by transmeridian time shifts, dislocation such as moving to a nursing home, and shift work. These may result in sleep disturbances with attendant problems with family, driving, and recreation.

It is obvious from the data presented that extensive studies need to be done to settle the question of benefits of treatment in these disorders. Carefully controlled studies of well defined clinical groups will be necessary to establish the benefit of various therapies. It is equally important in clinical trials to look at the efficacy of different means of sleep hygiene practices, not only for therapy but for prevention.

Added knowledge about the effectiveness of treatment should spur studies of cost effectiveness of diagnostic methods and therapies.

In all the areas mentioned there are many opportunities for basic and clinical research. The enhanced interest in the older population should provide both challenges and opportunities for investigators.

Conclusions and Recommendations

- There is a need for epidemiologic investigations of sleep disorders: case control, cohort, and cross-cultural studies should be initiated. The information developed in these studies will aid in the understanding of the natural history, etiology, and prevention of sleep disorders.
- Evaluation of sleep disorders begins with careful clinical evaluation performed by an informed primary-care physician.
- Standardization of clinical measures and assessment of the specificity and sensitivity of diagnostic procedures is essential.
- Advanced skills and diagnostic tools are available and should be applied in appropriate patients.
- The objective of sleep disorder therapy is to reduce morbidity and mortality and improve the quality of life.
- Obstructive sleep apnea is a potentially severe and treatable cause of daytime hypersomnia.
- Restoration of airway competence is the objective in the treatment of severe sleep apnea.
- Insomnia is a complaint with multiple causes and requires different treatments.
- Hypnotic medications should not be the mainstay of treatment of insomnia, are overused, and have habit forming potential.
- The value of good sleep hygiene should not be underestimated in the prevention and treatment of insomnia.
- Widespread knowledge about sleep and its disorders is lacking, and education at all levels is needed.
- The Public Health Service must take an active role in educating the public.
- Powerful new techniques, such as brain imaging, molecular biological tools, and neurochemical analyses, should be used in human studies and animal models to explore the basic mechanisms of sleep and sleep disorders.
- Sleep disorders in older people offer unique opportunities to study integrative neurologic, psychiatric, and cardiopulmonary functions.
- Current and new therapies and technologies must be evaluated by randomized controlled clinical trials.
- The Health Care Financing Administration should review current reimbursement policies, and continue to explore clinical data set requirements as these reimbursement policies for sleep disorders evolve.

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Speakers were:

Sonia Ancoli-Israel, Ph.D., A.C.P., "Critical Review of Epidemiological Studies on Sleep Apnea"

Edward O. Bixler, Ph.D., "Sleep Laboratory Studies of Insomnia: Specificity and Sensitivity"

Donald L. Bliwise, Ph.D., "Clinical Consequences of Sleep Apnea for Cognitive Functions"

Mary A. Carskadon, Ph.D., "Daytime Sleepiness: Clinical Consequences and Treatment"

Charles A. Czeisler, M.D., Ph.D., "Disorders of Circadian Function: Clinical Consequences and Treatment"

William C. Dement, M.D., Ph.D., A.C.P., "Disturbances of Sleep in the Older Person: Overview of Age-Related Changes in Sleep"

Irwin Feinberg, M.D., "Future Research Directions"

Christian Guilleminault, M.D., "When to Test? Indications for Evaluation"

Edward F. Haponik, M.D., "Attitudes on Sleep Disturbances of Older Persons by Health Professionals"

Anthony Kales, M.D., "Clinical Diagnosis of Sleep Disorders"

Daniel F. Kripke, M.D., "Periodic Movements in Sleep: Clinical Consequences and Treatment"

Merrill M. Mitler, M.A., Ph.D., "Insomnia in the Chronically Ill"

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Allan I. Pack, M.D., Ph.D., "Where to Test? Ambulatory Monitoring or Sleep Laboratory: Cost Effectiveness and Test Validity"

Charles P. Pollak, M.D., "Clinical and Social Consequences of Disordered Sleep"

Patricia N. Prinz, Ph.D., "Sleep in Alzheimer's Dementia and in Healthy Not-Complaining Seniors"

David M. Rapoport, M.D., "Nonsurgical Treatment of Obstructive Sleep Apnea Syndrome"

John E. Remmers, M.D., "Indications and Rationale for Treatrment of Sleep-Disordered Breathing in Older People"

Charles F. Reynolds III, M.D., "Subjective and Objective Sleep Complaints in Late Life"

Howard P. Roffwarg, M.D., "Common Sleep Practices and Myths"

Thomas Roth, Ph.D., "How Should Treatment Efficacy Be Monitored?"

John W. Shepherd, Jr., M.D., "Surgical Therapy for Sleep Apnea"

Michael J. Thorpy, M.D., "Classification and Definition of Sleep Disorders"

Phillip Westbrook, M.D., A.C.P., "The Treatment of Sleep Disorders in Older People: Educating the Health Professional"

Vincent Zarcone, M.D., "Education To Improve Sleep Hygiene"

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National Practitioner Data Bank Begins

AMERICAN MEDICAL NEWS

NEARLY four years after it was authorized by federal law, the National Practitioner Data Bank is about ready to begin operation.

Mandated by a 1986 law to protect the public from incompetent health care practitioners, the data bank will store information on actions related to professional conduct and competence, licensure status, and malpractice payments.

The bank, set to open Sept. 1, is being eyed cautiously by the medical profession. On one hand, the profession is only too happy to embrace a process that will help rid medicine of bad players. On the other, it deeply fears a project of this magnitude will suffer from breaches of confidentiality, especially in the area of malpractice payments, causing irreparable harm to the reputations of good physicians.

The AMA and other health groups have been working closely with members of Congress and federal officials to make sure physicians' and hospitals' concerns about potential confidentiality breaches and liability issues were addressed. The Health Resources Services Administration (HRSA), part of the Department of Health and Human Services, is the federal agency responsible for overseeing the project.

Although still negotiating some issues, the AMA was able to secure an amendment to the original legislation that severely limits conditions under which attorneys could have access to data bank information. Medical groups also reached agreements with data bank officials that would allow doctors to voluntarily enroll in impaired physician programs without penalty, and to allow voluntary, informal mediation programs administered by medical societies to remain confidential and not reportable.

The AMA has published a 12-page booklet for members to explain how the bank operates and how it will affect them.

Hospitals and other health care entities will be required to query the bank before hiring medical staff or granting clinical privileges. They also must query the bank every two years to check the status of current staffers and privilege-holders. Those that don't will be out of compliance with the law and will lose any protections otherwise granted.

Reportable Actions

There are four types of actions that must be reported to the bank:

- Medical malpractice payments: All payments made on behalf of any licensed physician as the result of a written claim or judgement must be reported to the data bank and appropriate state board of medical examiners within 30 days.

If a physician makes a payment to a patient because of a written claim or judgement, the doctor is responsible for filing a report with the data bank. Also, if an MD makes a liability insurance deductible payment directly to a patient, he is required to file a report, even if the insurance company pays the bulk of the settlement. The company also is required to report.

Malpractice payments made solely on behalf of a clinic or hospital, as opposed to one or more physicians, are not reportable.

If a payment is made in the name of a supervising physician for a claim based on a subordinate's services, both parties are named and reported. The reporting entity may provide further explanation of the extenuating circumstances.

The waiver of a patient's bill following the informal mediation of a complaint is not reportable. An exchange of money must be involved.

Even if the terms of the malpractice settlement require confidentiality, the malpractice payer must report the payment to the data bank.

- Licensure actions taken by state medical boards: Each board must report to the bank any disciplinary action based on a physician's professional competence or conduct within 30 days of the actions being taken.
- Clinical privilege actions: Hospitals and other health care entities must report to state medical boards (which then must report to the bank) when certain adverse actions are taken against doctors' clinical privileges. These include any professional review action based on the physician's competence or conduct that could or does negatively

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American Medical News is the weekly newspaper of the American Medical Association. This article appeared in the 27 July 1990 issue, authored by Diane M. Gianelli of the *A M News* staff.

affect the health or welfare of a patient, and that results in the denial, revocation, suspension, limitation, or reduction of the doctor's clinical privileges for more than 30 days.

Also reportable is the surrender or restriction of clinical privileges by a doctor under investigation by a health care entity relating to possible incompetence or improper professional conduct, or in return for not conducting an investigation.

Hospitals and other entities have 15 days from the date an adverse action is taken to report it to the state board of medical examiners. The board in turn has 15 days to report it to the data bank.

Adverse actions against physicians are not reportable until finalized by the health care entity, to give physicians notice and an opportunity for a hearing. If the entity's bylaws allow for an appeal preceding the final action, the action is not reportable until the appeal is settled.

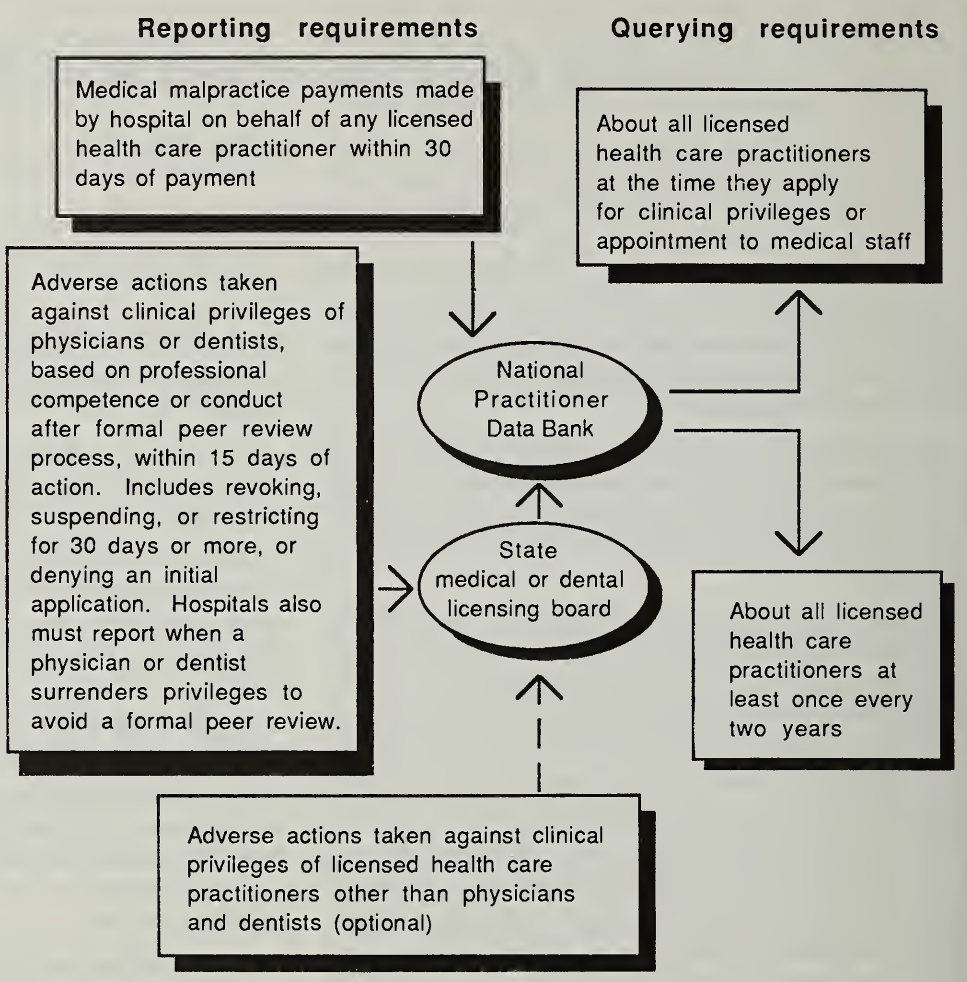
If an adverse action has been reported and later modified or vacated, the health care entity would be required to file a revised report with the bank.

Voluntary enrollment in a substance abuse or psychiatric rehabilitation program is not reportable if the hospital takes no action against the physician's privileges. What would be reportable is the suspension of a physician's clinical privileges for more than 30 days after a formal review related to professional competence or conduct.

Hospitals are also required to report when they have denied privileges to applicants or granted privileges more limited than those requested, if those denials or limitations are based on a professional review action and relate to professional competence or conduct.

- Professional societies of physicians: Groups such as the AMA, which engage in professional review activities through a formal peer review process, must report adverse membership actions to the data bank.

How hospitals will interact with the data bank


Reporting requirements
Querying requirements
Medical malpractice payments made by hospital on behalf of any licensed health care practitioner within 30 days of payment
About all licensed health care practitioners at the time they apply for clinical privileges or appointment to medical staff
Adverse actions taken against clinical privileges of physicians or dentists, based on professional competence or conduct after formal peer review process, within 15 days of action. Includes revoking, suspending, or restricting for 30 days or more, or denying an initial application. Hospitals also must report when a physician or dentist surrenders privileges to avoid a formal peer review.
National Practitioner Data Bank
State medical or dental licensing board
About all licensed health care practitioners at least once every two years
Adverse actions taken against clinical privileges of licensed health care practitioners other than physicians and dentists (optional)

Source: Dept. of Health and Human Services

The data bank is required to inform physicians of any report filed against them. It is also required to send any physician who requests it a copy of his or her own file.

In addition to hospitals, other parties allowed to query the bank include state licensing boards and health care entities that provide health care services and have a formal peer review process. Does this include managed care organizations? The answer is "sometimes yes, sometimes no," said Stan Bastacky, DMD, deputy director of HRSA's division of quality assurance and liability management. "If they provide health care and engage in professional review activities through a formal peer review process, then they qualify," he said.

Dr. Bastacky added that many health maintenance organizations would probably qualify, but most preferred provider organizations and independent practice associations wouldn't meet the basic criteria, and therefore wouldn't qualify.

In general, lawyers do not have access to any information contained in the data bank unless a hospital neglected to query the bank about the practitioner in question. In that case, information obtained from the bank on the practitioner can be used only against the hospital.

On the other hand, if the report lists information about sanctions against a particular individual, attorneys would probably have access to that data from other sources, such as state medical licensing boards.

Nonreportable Actions

Example of adverse actions that are not reportable because they are not based on a doctor's professional competence or conduct include:

- Suspensions of a physician's clinical privileges or staff membership for failing to complete medical records on time, providing patient care was not compromised.
- Denial of privileges because of a lack of need for the physician's services, such as a closed medical staff or an exclusive contract.
- Suspension, denial, or nonrenewal of privileges or staff membership because of failure to secure or maintain a specified level of professional liability insurance.
- Denial of privileges or staff membership due to failure to comply with threshold eligibility requirements such as board certification or geographic requirements.
- Denial or nonrenewal of privileges because of failure to meet new threshold requirements (such as board certification) or lapse in a requirement (such as Advanced Cardiac Life Support Certificate).
- Reduction or nonrenewal of privileges for failing to meet hospital credentialing requirements, such as the need to admit a minimum number of patients.

Hospitals are not required to query the bank on interns and residents, because they are "trainees" and are not formally granted clinical privileges or considered members of the medical staff. Hospitals are, however, required to query the bank about residents and interns hired to work outside their regular program, such as those who "moonlight" in another department, because they are, in that context, considered staff.

Any malpractice payments made on their behalf or adverse licensure actions taken against them also must be reported.

Disputing Information

Physicians have 60 days to dispute information in their data bank file if they believe it to be inaccurate. To do so, they inform the Health and Human Services secretary they disagree with the report and wish it to be entered into a "disputed" status. They describe in writing the nature of the disagreement and return it to the data bank.

They also must inform the reporting entity in writing of their disagreement with the report and try to resolve the dispute at that level.

If the reporting entity agrees to correct or void the report, the data bank is informed and the disputed report corrected or deleted from the file. If the dispute is not resolved, a notation is placed in the file, and all who query the bank about the physician in question will be notified that the information is being disputed by the doctor.

If the reporting entity does not revise the disputed information, the HHS secretary will, upon request, review the case and determine whether the information is accurate or inaccurate. The secretary will not, however, determine the merits of the claim or the appropriateness of the professional review action in the report.

If the secretary determines the report is incorrect, the disputed information must be corrected. If it's determined that the information should not have been reported, the report will be voided. If the information is determined to be accurate, the secretary will submit for the file a written explanation of the basis for that decision. The physician will be allowed to file a statement with the report describing the disagreement. All parties involved—queriers, the physician in question, and the reporting entity—will be informed of the dispute's resolution.

Confidentiality

Data bank information is confidential and available only to authorized entities. Violators will be subject to civil penalties of up to $10,000 per violation and criminal penalties of up to $25,000 and five years in prison.

When asked what could stop a plaintiff's attorney or an insurance company from "pretending" to be a legitimate health care entity by making up phony stationery and applying for a "code" to get access to bank information, HRSA's Dr. Bastacky said, "Only the chance that they will be caught." The civil and criminal penalties "are pretty steep," he added.

He said it was likely someone trying to obtain information fraudulently would be caught, since physicians can ask the bank to disclose who has asked for information on them."If it's someone who shouldn't have access,"Dr. Bastacky said, "he'll know immediately."

Victor's Secret

MICHAEL T. KOVALCHIK, M.D.

VICTOR sits across from me, and I reflect on all the experiences we have been through together: decompensated cirrhosis, LeVeen shunt, hepatic encephalopathy, two thoracotomies for lung cancer, uncontrolled diabetes mellitus, acute renal failure, and GI bleeding. In addition, his wife died unexpectedly and he was still struggling with her loss. He had a twinkle in his eye and a gentleness about him that attracted me. I always looked forward to our meetings. Today I observed that his vitality was gone and the spark of life so characteristic of him was extinguished. I commented and he appeared sad. He looked at me for a moment and spoke softly and carefully.

"You know, Doc, I used to give my wife a lot of grief about the way she did things. The way she drove the car, prepared the meals, cleaned the house and so on. Now that she is gone I realize how much I enjoyed her ways and how much they meant to me as they represented her uniqueness. I am just so sad that I never told her that I loved her for all those special things she did."

I reflected for a moment. Victor had shared with me his secret. He was carrying it with him, like a touchstone, so he could come back to it and touch his pain. For him, it was a locked room and only he had the key. Yet today, he shared his secret with me. How many more secrets were out there? For in the secret lies the key to the room. If the physician can touch the key, he can help the patient rebuild his life. How many secrets had I missed or failed to see? How many secrets remained buried because I was not open to the patient? Why do we require life-threatening experiences to expose our secrets? Why, as I had so often observed, do these experiences allow patients to begin to feel and experience life in a totally different manner?

I remembered the lyrics of a popular song by Paul Simon:

> There is a wall in China 1,000 miles long,
> To keep the foreigners out, they built it strong.
> There is a wall around me that you can't even see.
> It takes a little while to get next to me.

Instantly, images of my first days in medical school flashed through my mind. Enthusiasm was contagious. We were taking the first step in developing a bond with mankind. What closed our eyes, what deafened our ears, and what locked our hearts? What happened to that enthusiasm? Over time, I observed it dissipate in myself, my classmates, my fellow interns and residents, as well as faculty members. Did our role models fail us? Models are important as they provide a context for the exploration of a range of experiences and phenomena. But in human terms, models can never replace the ebb and flow of our feelings and intuitions as they coalesce with our skills and knowledge. Our models are not true mirrors, they do not reflect back who we are. If we accept that models reflect who we are, we lose our identity.

I recalled "rounds." The accent was on facts, information, references, and to some extent posturing. Those who talked the fastest and with the most authority made the biggest impact. As our processions left the patient's room, I frequently felt compelled to lag behind and hold the patient's hand, providing reassurance and I would be back later to answer any questions. I observed compassion competing with the glamor and excitement of the rounding team. How could or hearts compete with the quick-witted, knowledgeable, citation-quoting physician who at a moment's notice could field inquiries from anyone and come up with a plausible explanation fully referenced? Who was there to teach us to look into our patients' eyes in order to sense and feel their pain and suffering? Who was there to teach us to listen with compassion so we could learn from our patients? I recalled Osler's comment: "It is more important to know what kind of person has a disease rather than what kind of disease a person has." His voice seemed to be a lost echo in the corridor as we chased the elusive reference and devoured the most recent journal issues. Our minds were drowning out the soft voice of compassion within ourselves asking to be heard. Quietly, over a long period of time, we built a wall around ourselves. Insular and confident, we approached our careers. Our models had taught us well.

Victor's secret had reminded me of my long struggle with the wall. Recognizing it had been a difficult challenge. Often as I faced a patient, those feelings, at a

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MICHAEL T. KOVALCHIK, M.D., Director of Dialysis, Charlotte Hungerford Hospital, Torrington.

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seemingly unconscious level buried deep within, tried to surface. I was an expert in thwarting their expression. Occasionally, my barriers would fail and I would come face to face with those deep emotions aroused by pathos, pain, and suffering. What to do with them? My models had not prepared me for this. Was I experiencing something unique to myself, unknown to other physicians? I began to wonder whether I was losing my clarity along with the necessary detachment to solve complex medical problems. Finally, I recognized the true nature of those feelings. They were real, legitimate responses to very difficult and demanding circumstances. Initially when they came forth, I felt uncomfortable because I believed I was alone. In the teaching setting, our human responses to our patients and their problems were rarely at the forefront of discussion. In addition, those responses were uncomfortable and shifted the focus away from the immediate task at hand. I learned to put them aside. I would deal with them later. Consequently, I entered the DMZ of medical practice, my armor carefully chosen and well-fitting.

Now as I shed my armor, I recognize the call of humanity within myself. At first, I was confused and unsure as to the nature of the call. I observed my responses and especially my feelings and intuitions in a variety of clinical situations. Finally, I took the plunge. I began to go with my feelings and ultimately came to trust them. My relationships with patients changed. I discovered that I needed my eyes to see, my ears to hear, and most importantly, my heart to respond. From this perspective, I could see and hear better and patients seemed to respond better. Most importantly, however, an awareness of the sanctity of work surfaced. The flower of the doctor/patient relationship blossomed and real satisfaction came from very simple day-to-day clinical experiences. The tension and fatigue brought on by the day in and day out encounters with patients with acute and chronic illness began to lift. At times in my daily encounter, I was aware of receiving more than I gave.

My disarmament had been a gradual process but now it seems so simple. Feelings are recognized, accepted, and utilized, resulting in a smoother doctor/patient relationship. Each day of openness allows trust to enter. Once trust is at hand, the wall crumbles and the physician's world expands. Let in the pain, suffering, frustration, joy, beauty, and excitement of your daily experiences, and by feeling all of them perspective is gained. One begins to see things in their proper size and in their proper place. As Thomas Jefferson so eloquently stated, "It is neither wealth nor splendor but tranquility and occupation which brings happiness." When the walls are broken down, tranquility emerges and reverence for occupation can then occur. Victor and I talked. He expressed his feelings, especially his fears. I listened and at times smiled, for by listening I know that I could provide him far more than I ever could with my stethoscope, prescription pad, or laboratory request form.

Health Insurance for the Uninsured

On 1 July 1990, a new law that begins to alleviate the lack of insurance coverage for some of Connecticut's citizens, goes into effect. The law, 90-134, adopts a public/private partnership approach, expanding state-subsidized programs and instituting insurance market reforms. Nearly a fourth of Connecticut's 272,000 uninsured residents are expected to benefit. The priority populations are: pregnant women and children, the disabled, and the working uninsured, two thirds of whom are employed in the state's 80,000 small businesses.

The plan will expand access to 61,400 residents at a cost to the state of $24.3 million. To get the plan rolling the legislature has appropriated $2.4 million for FY 90-91 and has created the Health Care Access Commission to develop administrative and financing details for future program initiatives.

A key feature of the plan—developed with the insurance industry's help—is reform of the small business insurance market in order to help workers who are not being offered insurance or cannot afford it.

Other features of the law include:

- Extending Medicaid eligibility to children from age six to age eight, the elderly, and those with disabilities who fall below the poverty level.
- Implementing presumptive elegibility for pregnant women seeking Medicaid so that prenatal services can begin immediately.
- Having Medicaid pay the worker's share of health insurance premiums for low-income workers.
- Providing health insurance for pregnant women with incomes up to 250% of the poverty level.
- Increasing funds by about $4.4 million for preventive care services to low-income individuals.

Anyone who would like a copy of the law should call Kyle L. Ballou, Esq., Director of Government Relations at CSMS 865-0587.

Oh, My Achin' Back

E. TREMAIN BRADLEY, M.D.

THERE are several reasons for back pain, including intervertebral disc disturbance and some results of trauma. But more commonly the culprit is those big strong muscles that run from head to pelvis. One hears: "My back is out." Out where? Well, out of commission because of pain. Why?

I have told my patients something like this: Voluntary (striated) muscle is intended for strong, quick, relatively brief, intermittent action. Most of our external parts are paired, permitting alternation: one side, then the other side; contraction, then relaxation. When one skeletal muscle contracts, its opposing muscle is stretched out, ready for its turn to contract. To accommodate for the amount of energy expended, voluntary muscle must have a high rate of metabolism. Tightening the muscle squeezes out the blood and relaxation permits replacement with fresh blood, ready for anabolism. But the catabolic action of contraction has left waste products (ashes), notably lactic acid, which should be expelled with the next contraction.

But what if the muscle is maintained in contraction for a long time? Obviously waste products build up, and unfortunately tend to maintain the muscle in contraction—still metabolizing and collecting more ashes. If you try to stretch these muscles—which don't relax well—pain results. Pain is a warning signal of nature, sending the message: "On guard, protect yourself, tighten up." More contraction, more pain.

What starts all this? Two things come to my mind: posture and conditioning. Watch an infant walking. Pelvis is tipped way forward creating a concavity in the back when the head and shoulders are erect. When building a house, the foundation is made level so the bricks or cinderblocks lie one on top of the next and need very little support. The pelvis in an adult should be basically level too, so the vertebrae will lie directly and comfortably on top of each other. Otherwise, with the hollow in the small of the back, constant support is required by muscles held taught, predisposing to spasm and pain. Try elevating the symphysis pubis and tucking the coccyx down behind and under, as if "sitting on your legs." This automatically flattens out the hollow in the back and stretches those strong back muscles.

And conditioning—posture and voluntary muscles in general are intended to be dynamic, not static. Periodic shifting of position or other muscle activity will stimulate the flow and exchange of blood. Actually, a little routine each morning which takes every muscle through its full range of motion, and every joint simultaneously, will help maintain good metabolism in the muscles and prepare them for most demands of the day, even the unexpected ones. Power is not the objective primarily. It is avoidance of spasm, and the preparation for unusual, often sudden, stress.

Nice theory—but what to do about that pain? Go to bed? Stand or sit motionless and tense to avoid pain? No! Try to move a bit and if it hurts, note that limit and don't go beyond it. But walk, bend forward *a little*, try not to tighten up. This motion will allow fresh blood to "chew away" the waste products at the edges of the spastic mass, gradually reducing it. Find an activity which involves natural spontaneous functions. Keep moving, keep relaxed. Oddly enough, over the years I have had maximum relief by swinging an axe! The axe head did all the work and my muscles could relax. (I don't recommend this method for everyone.) Aspirin, bufferin, etc., even butazolidine may be needed. Mild heat and gentle massage may help.

Other frequent offenders are the leg muscles. Cramps are common at night. They also may attack athletes. Again, some relaxation alternating with contraction is important. Raising legs in the air—upside down bicycle riding—can help ward off cramps, as can ambling with legs "floppy," or passive stretching of the offender. If the cramp has already "seized," passive stretching with a slight pumping action tends to produce relief. A bit of gentle, deep massage can help melt away those knots of spastic muscle. By way of medication I use quinine sulphate, gr v, when needed during the night, or at bed time. Verapamil has also been found effective. One famous tennis player eats bananas.

As Andy used to say: "Unlax, Amos; unlax!"

E. TREMAIN BRADLEY, M.D., solo practice of General Surgery, retired to Norfolk.

Editorials

The National Practitioner Data Bank and Credentialing

As is always the case, AMA members have received early and accurate information of importance to all physicians through the weekly *American Medical News*. Thanks to the kindness of our CSMS editor, the AM News lead article, "The National Practitioner Data Bank Begins," appears on page 519 of this issue of *Connecticut Medicine* at my request, to assure its maximum exposure.

The importance of this new national information source relates entirely to the future, however, since it is not retroactive, and at present has no information at all. For the present, even though hospital credentialing committees will be required to "query the bank" before granting privileges to new medical staff (and every two years for existing privilege holders), it will be years before such inquiries yield much information. Only adverse actions occuring after 1 September 1990 are to be reported by hospitals, and then only after they have "finalized" the action by having given the physician notice and opportunity for a hearing and, if the bylaws allow, an appeal. Once reported, additional due process is available to the physician who may wish to dispute the report, and failing settlement, to request review by the Secretary of the Department of Health and Human Services. Thus it may be years before these queries will yield much information, and the bank's usefulness to hospitals assessed.

Fortunately the AMA has been gathering such information since 1906 to assist hospital medical staffs in the credentialing process. State medical boards have also established such a resource. The point is that those physicians having responsibility for hospital credentialing must continue to seek adverse information from the AMA Physician Masterfile and/or the American Federation of State Medical Boards' database when considering any applicant whose medical experience predates 1 September 1990. We have confirmed that both organizations will continue to gather and update their information. Upon appropriate inquiry the AMA Masterfile will issue letters of concern where adverse information is on file concerning a candidate for privileges. For responsible credentialing, the new HHS databank is no substitute for existing databases, despite its mandated standing.

In January 1985, *Connecticut Medicine* published a CSMS "Guideline Checklist" for the hospital medical staff credentialing process. It had been approved by the previous meeting of the Society's House of Delegates, and mailed to the CEOs and the medical staff presidents of all Connecticut hospitals. It was developed in response to a finding of the CSMS Committee on Hospitals that considerable variation existed in the levels of investigation utilized by credentialing committees in the various hospitals. Now, in response to the 1990 HHS regulations, a mandatory query to the National Practitioners Data Bank must be added to our checklist under "Derogatory Information." The CSMS checklist, with this change, is reprinted below for the information of all physicians subject to or responsible for credentialing.

Mehdi S. Eslami, M.D.
CSMS President

Waterbury, CT

Figure 1

Hospital Medical Staff Credentialing Process
CSMS GUIDELINE CHECKLIST
Elements of Documentation and Verification

Documentation	**Verification**
1. Education Training References Board Certification/Eligibility Previous Hospitals Medical Societies Licensure: Connecticut Other Jurisdictions	1. Physical Check Follow-up by Mail/Phone Check of Indirect References (2nd stage references) Contact for CT Licensure: (566-5296) SDHS Physician Licensure Bureau
2. Derogatory Information—Query: AMA Masterfile State DEA's State & County Medical Societies HHS National Practitioner Data Bank	2. Confront applicant if not mentioned in application or interview
3. Photograph	3. Photo verification with previous jurisdiction
4. P.L. Insurance Coverage	4. Check where appropriate
5. Previous Impairment	5. Confirm recovery
6. Discern gaps in background	6. Verify explanation for gaps

Guest Editorial

Insurance Companies Intrude in Doctor-Patient Relationships

As a person who rather joyfully catapulted from homemaker to internist, thereby reaching a lifelong goal, I am saddened to admit a growing disillusionment about the practice of medicine. I love taking care of patients, my internal medicine practice in South Windsor is most meaningful to me and the collegiality of fellow physicians at Saint Francis Hospital and Medical Center is satisfying. So what has gone wrong?

The issue is complex. Like many of my colleagues, I worry about being sued, but I try to practice good medicine and put this worry in perspective. What I have found more painful to accept, what has become unbearably discouraging, is the increasing intrusion of insurance companies, and Medicare, into the previously sacrosanct relationship between physician and patient.

In discussing this issue with my physician-friends, I find the same demoralization I am feeling, especially among my colleagues in internal medicine, family practice, obstetrics and psychiatry. The stories told are sad and disturbing.

An obstetrician told of a patient in need of an early delivery because of signs of impending toxemia, a condition that can threaten both mother and infant. A previous Caesarean delivery, combined with the risks of possible toxemia, convinced the physician that it was in the mother's and the baby's best interests to have another Caesarean, although under less worrisome conditions, a regular delivery could have been attempted. A specialist in delivery problems was consulted and agreed.

However, when the woman's Ohio-based insurance company was notified, a consultant on its staff, making all his decisions by telephone, decided the Caesarean operation was unnecessary and suggested he would not authorize payment. Only when the specialist called and demanded that the consultant take legal and moral responsibility for any delivery-related mishaps was the decision reversed.

Two internists each received a letter from health-maintenance organizations in the Hartford area. The internists were informed, in one case by a businessman hired by the HMO, that they were costing the organizations more "per patient per month" than their "peers." One was told he was doing too many throat cultures and complete physical examinations, while the other was advised her referrals were costing the company too much money and she was seeing her patients an average of 3.33 times a year (compared with her "peers" who saw HMO patients 2.47 times a year). This latter accusation, she pointed out, was from a company that advertises "unlimited" office visits to one's primary-care physician.

Both physicians were threatened with cuts in pay if they did not provide good explanations. This would not be so alarming a story if these were not highly respected, competent and compassionate doctors trying to give high-quality care to their patients. Both are more committed than most to preventive health care which, unfortunately for them, is known to cost more in the short run. The HMO's computers were not so sophisticated enough to estimate how much these internists might be saving the company in years to come.

What effect does such intimidation have on the physician-patient relationship?

One of the internists believed he could not practice with integrity under such pressure and left the HMO. The other pointed out to the HMO that because 85 percent of her patients were women, her monthly costs should be expected to be higher because women are known to go to the doctor more often than men and require more expensive preventive care, such as mammograms, PAP smears and yearly red-blood counts. Almost two months after submitting her explanation, she still had not heard if the HMO planned to cut her pay.

She does relate, though, a sense that her relationship with her patients in that HMO has been damaged, because she is now aware that any test she orders on their behalf, or any referral she makes, is being "charged" against her on some distant computer.

When such things happen to colleagues, all doctors are affected. Personally, I am proud that my percentage of female patients who have had timely mammograms is double the state average, but now I worry that these may be counted against me. Even while physicians remain dedicated to providing excellent care to patients, it does seem morally wrong that they should feel "pitted" against their patients.

The biggest problem we face with such disillusionment among primary-care physicians, those in internal medicine or family medicine, is that they are leaving practice at an alarming rate. I personally know 12 doctors, half in their 30s, who have left private practice in the past several years.

Young men and women are much less likely to choose medicine as a career today. There are fewer applicants to medical school and the quality of aspirants is falling. Those who decide to go to medical school tend to avoid the primary-care fields because the pay is relatively low and

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the hassles are enormous. Despite what you may read, there are many of us making $50,000 to $80,000, much of which goes to pay educational and start-up debts, which often exceed $100,000. We routinely work 60- to 80-hour weeks, including nights, weekends and holidays.

We do not have the national resources to pay for complete and perfect medical care for every citizen. Health care must be rationed in some way. Oregon is trying to make such decisions logically, with public input, rather than the hap-hazard attack now being taken by insurance companies and the Medicare bureaucracy. Their approach is the ultimate conflict of interest: Those who are footing the bill are deciding how much care individuals receive.

We must develop a system in which decisions about how health care is delivered are made by people who have nothing to gain or lose from their decisions.

This is especially critical when a judgement goes against what a physician has decided is best for the patient. We could be a little more philosophical about a challenge to our judgement, and perhaps even learn from it, if the challenge came from a panel of impartial physicians, rather than from an insurance company that simply does not want to pay the bill. I would imagine patients would prefer such a system, too.

Physicians themselves must have the courage to chastise those in their ranks who order tests or do procedures that are more for their own profit than the patient's good. Ours is still a noble profession, but it will not remain so if we begin to value income over integrity.

Above all, we cannot afford to be penny-wise and pound-foolish. Every solution considered must have provisions to prevent the burnout of a whole generation of dedicated primary-care physicians. Failure to do so is a cost we simply cannot afford.

Karen S. Devassy, M.D.

South Windsor

Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1 ½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

LOVE AND SERVICE

To the Editor: Dr. Lawrence Kleinman's sensitive article concerning the suffering of poor children in Connecticut, one of the richest areas in America if not in the world, points to a fundamental loss of spiritual commitment on the part of a large segment of our marvelous profession to care for our neighbor and to love him or her as we love ourselves. Back in the old days, the late 1940s and 1950s, and they were not necessarily the "good old days," in order to be member of the staff of a hospital, a physician or surgeon was required to care for the indigent poor and the aged for free as a duty implicit to staff privileges. Generally, staff physicians took care of one and all happily without regard to financial status. The advent of the Medicare and Medicaid programs put an end to the provision of this type of service. As Dr. Kleinman has pointed out some practitioners have seen fit not to accept patients enrolled in these programs. The rate of remuneration is certainly minimal when compared to regular charges for medical services. But is this sufficient reason to withhold service?

At a breakfast sponsored by Danbury Hospital honoring a group of us older practitioners who were winding our practices down, I suggested that some of us should band together to offer free clinic services to the community poor. There was wild applause but that was nine months or so ago and nothing further has been forthcoming with that idea. The biggest drawback is providing for liability insurance coverage for those who wish to work just a few hours a week. With support from local political officials this problem probably could be worked out satisfactorily.

In the meantime, feeling grateful for a satisfying and rewarding career spent in a general surgical practice in Danbury, I am bent on another leg of the journey. As a witness to the profound suffering of those afflicted with the disease of dependency on psychoactive chemicals, I am moved with compassion for them. They, like the poor children of Bridgeport, have few, if any, advocates. They are discriminated against and stigmatized. Adequate treatment is provided only to a limited degree, witness the impediments to methadone substitution therapy for opiate addicts imposed by our addictophobic society.

Management of addiction to prescribed chemicals is remanded to the police and the criminal justice system rather than to the medical care system where it belongs. If one is addicted to alcohol, a legal chemical, treatment can be obtained with preservation of anonymity and confidentiality in a medically oriented ambience. Not so in the public methadone programs. Addicts need advocates to lobby for rational changes in the manner in which their problems are handled. For instance, relapsing, opiate dependent individuals need accessible, unrestricted, pharmacological treatment with methadone to allay craving, to prevent withdrawal symptoms, to avoid IV use with the high risk of AIDS and, most of all, to gain a functioning life style.

Dr. Bob Smith, the cofounder with Bill Wilson of AA, at the National AA convention immediately prior to his death from colon cancer, said simply and briefly that it's LOVE and SERVICE that count. Try it. It's fun. It works.

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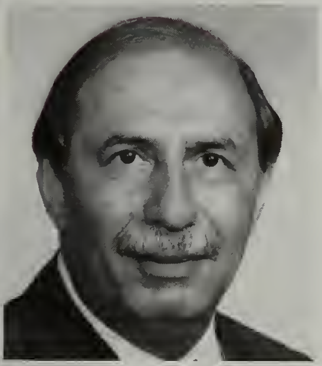
To Get a Friend, Be a Friend



On November 6th, Connecticut will vote for all six Congresspersons, a Governor and all 187 members of the State House and State Senate. All of these officials will have much to say and do on issues of crucial importance to us and our patients. There is a great deal that we as physicians can do to let our views be known. But we have to get involved personally.

Meet the Candidates - You can arrange a function (cocktail party, clam bake, or just a meeting) with other physicians to get to know a candidate and discover his or her views on issues. At the same time, you can let him or her know your views on issues and legislation, and how they affect your practice and, most importantly, how they affect your *patients.*

Moreover, consider inviting candidates to tour your practice and to meet your staff. This gives the candidate a better idea of what it actually means to run a practice and to get a 'feel' for what your patients encounter.

Work for a Candidate - If you feel strongly about a particular candidate, and you have time that you would like to volunteer to them, contact them or their campaign headquarters. There's always work to be done and the candidate would be grateful for the assistance. Let physicians be a visible and friendly presence in a political campaign of your choice.

Contribute to a Candidate - You can make a personal monetary contribution of support to a candidate's campaign. Also, you can contribute to COMPAC, the political action committee whose members are also members of the Connecticut State Medical Society. COMPAC gives financial contributions in over 100 of the state legislative races and the gubernatorial race. However, according to the law, you must give a *personal* check.

Make Sure You are Registered to Vote - October 16 is the last day that you and your staff may register to be eligible to vote in the November elections. The exceptions to this deadline include a person who becomes a U.S. citizen, who moves to another town, or turns 18 before November 6. Usually, the registrars of voters in municipalities schedule evening and weekend hours before October 16. The importance of your registering to vote, and then *voting*, cannot be emphasized enough. Encourage your staff to register and vote. If you or they will be out of town on November 6, you may get an absentee ballot by calling the registrar of voters in your municipality.

A few hours and dollars invested *now* will pay dividends later when the General Assembly is reviewing legislation that will affect you and your patients. Invariably, legislators will remember you as a friend, and as a knowledgeable, familiar and welcome resource for information on health care issues.

We have learned long ago that medicine needs many more friends on the hill.

Mehdi S. Eslami, M.D.
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Exasperating the Ways of Death

ROBERT U. MASSEY, M.D.

THE days of our years are three score years and ten; and if by reason of strength they be four score years, yet is their strength labour and sorrow; for it is soon cut off, and we fly away. (Psalm 90:10)

Several years ago in preparation for a talk on life expectancy, I looked up the ages at death of physicians in the 19th century. Using Garrison's *History of Medicine,* I noted the age at death of those who had died between 1800 and 1914, the "long" 19th century. Of course, all were male, European or American, and all had lived beyond the age of 35, otherwise they would not have achieved sufficient fame to be memorialized in a history text. Their number was 98 and their mean age at death was 70.5 years. Had I done the same for writers or musicians the outcome would have been somewhat different for artistic fame comes earlier in life; in fact, for the 45 English poets in *The New Oxford Book of English Verse* who died in the 19th century, the mean age was 62 years. The obituary section in *JAMA* for 1 August 1986 reported 96 physician deaths over age 35; their mean age at death was 71.4 years, only 11 months older than the 19th century crowd.

Looking at averages hardly constitutes sophisticated statistical analysis, and these figures should not be made to carry such unwarranted implications as: we apparently have achieved very little in medicine in the last 100 years if all we can show for it is an increase in longevity of less than one year. We should, however, not be surprised that the Psalmist's experience of adult mortality in the middle of the first millenium B.C. was not essentially different from ours. We know that most of the gain in life expectancy during the last 150 years derives from a sharp reduction in deaths in infancy, childhood, and early adult life. That would hardly have affected the life span of well-known physicians, politicians, or orchestra conductors in any century.

Most of us recall only the Psalm's "three score years and ten" clause; the labor and sorrow of the eighth decade is understandably overlooked; indeed, for some those years are golden, not laborious and sorrowful. But in truth for more than a few of us the last years will be boring, lonely, uncomfortable, even cruel, in spite of the very best efforts of those who, out of love or pity, will care for us or, for reasons of duty, must provide for our physical needs.

> *With what strift and pains we come into the world we know not, but 'tis commonly no easy matter to get out of it:. . .*[1]

From his own experience as a physician Thomas Browne well knew this truth about our mortality, and seemed to be deeply troubled by it for he repeated these lines in almost the same words in *Christian Morals*, and then added:

> *Many have studied to exasperate the ways of Death, but fewer hours have been spent to soften that necessity.*[2]

After 300 years we physicians have indeed learned to exasperate death in ways that Browne would never have imagined; it may now be our bounden duty to tell our patients how they by taking thought may protect themselves in their final days both from us and from the meddlesome intrusion of the state. The case of Nancy Cruzan has made it clear that the state may require that the ways of death be exasperated unless there are clear instructions from the patient requesting that we restrain our heroics and "soften that necessity." It is, I believe, we who shy from speaking of our mortal enemy; many patients in the late autumn of their lives are quite prepared to speak of death as their mortal friend and wonder why their doctors never mention it. They know that the three score years and ten are usually healthy years, but that the next decade or two may not be. Some, perhaps most, of them are repelled by the thought of life at any cost, and want desperately to make sure that they will not be forced to stay and pay for what they neither want nor need.

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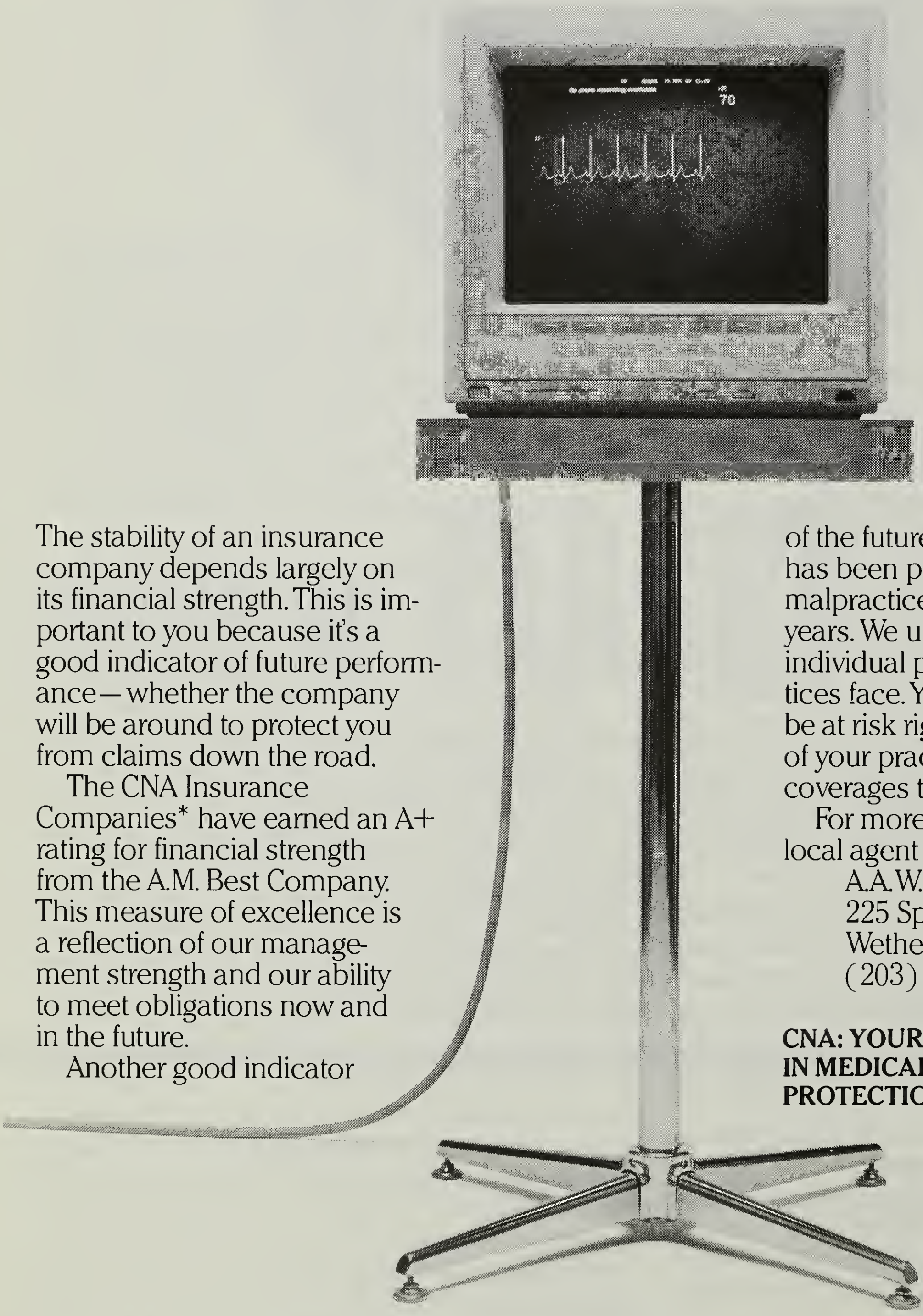

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The Abortion Czar

JOSEPH M. HEALEY

IN a particularly insightful article[1] on the United States Supreme Court's consideration of abortion in the *Webster* case[2] during the 1988-89 term, George Annas described the unusual position that Justice Sandra Day O'Connor has created for herself:

> Justice O'Connor continues to suggest that the Court adopt her own personal test for determining the constitutionality of state abortion laws: does the regulation "unduly burden" the woman's right to seek an abortion? Thus the opinion can rightly be seen as 4-1-4 on the issue of reversing or severely curtailing *Roe*. What has been insufficiently appreciated is that the Court, with this opinion, implicitly appoints Justice O'Connor, the only woman to sit on the Court, as the nation's 'Abortion Czar.'[1(p28-29)]

The impact of this unusual situation can be seen in the Supreme Court's handling of two abortion cases decided during the 1989-90 term in which two states' statutes (Minnesota and Ohio) regulating minors' access to abortion by requiring parental consent or notification were decided by narrow majorities. In each case, Justice O'Connor provided a key vote. Ironically, in one case, she provided the vote needed to uphold the statute, while providing the vote needed to find portions of the statute unconstitutional. These cases emphasize once again the difficulty in formulating a coherent public policy with respect to abortion.

In the first case,[3] the Minnesota statute prohibited the provision of abortion to a minor until at least 48 hours after both parents had received notification of her intent. Such notice was required unless: (1) the abortion was necessary to prevent the patient's death and there was insufficient time to notify her parents; (2) both parents had consented to the procedure in writing; or (3) the woman declared that she was the victim of abuse, neglect, or sexual abuse. Under this third exception, the appropriate welfare or law enforcement agency must be notified. The Federal District Court for the District of Minnesota held the statute unconstitutional in its entirety and enjoined its enforcement. The Court of Appeals for the Eighth Circuit reversed, rejecting the claim that the 48-hour period was an impermissible burden on the minor's right to an abortion and holding that the provision for judicial bypass of parental consent contained in a contingency section of the statute designed to take effect if the parental requirement provision were held unconstitutional, was sufficient to keep the statute constitutional as a whole.

In the second case,[4] the Ohio statute prohibited the performance of an abortion for a minor unless (1) one parent had consented in writing; (2) the physician had given notice to one of the parents; (3) the court had authorized an abortion because the woman was sufficiently mature, the victim of parental abuse, or notice was not in her best interest; or (4) if by its inaction, the court provided "constructive" authorization. The Federal District Court and the Court of Appeals for the Sixth Circuit both concluded that provisions of the statute were unconstitutional and enjoined its implementation.

Both cases were appealed to the United States Supreme Court and decided as companion cases on 26 June. In the first, one majority of the justices held that the requirement that both parents be notified was unconstitutional. However, a different majority held that the contingent judicial bypass provision preserved the constitutionality of the statute. In the second case, the majority concluded that the Ohio statute did not impose an unconstitutional burden on the minor seeking an abortion.

Discussion of these cases will continue in next month's column.

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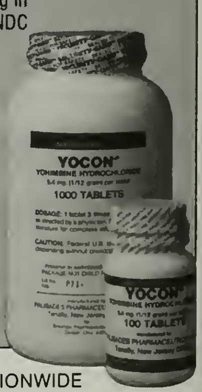

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From the *Journal of the Connecticut State Medical Society*

September 1940

Medical Preparedness in Connecticut

CREIGHTON BARKER, M.D.
New Haven, Conn.

The logic of present rapidly moving events again brings into sharp focus the importance of medicine in every pattern of human affairs. It was only a little while ago, although it seems remote, that medicine was directing its attention to rearrangement of its age old method for providing medical care for our people. This question has by no means been answered but suddenly we find ourselves confronted with new and complex demands arising from an unprecedented preparedness program and the unpleasant anticipation of the necessity for defense of our country. Medicine at once finds itself in the forefront of that effort and the national health takes on new significance as a powerful military weapon. Man power and machines are the things that are counted on, but underlying them both is the physical and mental well being of the citizenry.

As we look back upon the events of the last war many shortcomings and inadequacies of preparation come quickly to mind and it seems certain that this time we ought to profit from previous mistakes. It is slow work at best and from it all blunders cannot be eliminated, but many of them will not be repeated.

The medical military authorities of the country have already sought the cooperation and counsel of the American Medical Association and the Association has sent a resolution to the President of the United States and the National Defense Commission asking the immediate appointment of a medical coordinator of all medical services related to the National Defense Program. The Association has proceeded with the establishment of a National Committee on Medical Preparedness and that Committee spreads fanwise into every state with a state chairman on medical preparedness and subordinate units in each county. This organization has been completed in Connecticut and its functions are being carefully considered and weighed so that the most important things will receive the first attention. All the activities fall with some clarity into three catagories no one which is separable from the others but must be worked out along independent lines.

The first of these is supplying medical and medical-technical personnel for the armed forces and the physical selection of man power. Until the army and navy are expanded to a size beyond a point that does not appear to be contemplated, supplying physicians should not present a great numerical problem but the qualifications of the medical men entering the services should be viewed with fine discrimination so that the most efficient personnel will be available to meet the highly specialized needs. With the operation of a selective service law, comes the demand for doctors to serve on the selective service boards. It is obvious that the choice of this personnel should be left to the medical profession itself for in no other place can the understanding knowledge of the availability and skill of physicians be found. The Connecticut State Medical Society has already volunteered to meet this responsibility.

Second, the needs of the civilian population must be met and medical care for the public continued without impairment. This will call for a knowledge of which physicians can be spared from their civilian pursuits and may occasionally require the tactful discouragement of patriotic motives on the part of individuals who do not realize that the field of their greater service is at home, communities and hospitals must not be deprived of medical service. The American Medical Association has requested the National Defense Commission and the Congress, in preparing for conscription, to provide for the continuation of medical education and for exemption from conscription of all medical students and internes in accredited and approved hospitals.

A new civilian demand will inevitably present itself in the increased vigilance that must be directed toward the maintenance of health and efficiency among industrial workers. The program of material production may be greatly handicapped by loss of time arising from accidents and occupational hazards. There are many new industrial processes that present chemical and ventilation problems that are as yet only partially understood, and physicians, chemists and physiologists must be relied upon to solve these. An interesting and far reaching training program in this field is in the process of development by Yale University, a program in which The Connecticut State Medical Society and the State Department of Health welcome the opportunity to cooperate. Emotional effects will surely come with industrial speed-up, and personnel experienced in the field of preventive psychiatry will be called upon to meet these problems. The Committee on Medical Preparedness of the American Medical Association has recommended to the National Defense Commission that funds be furnished to the United States Public Health Service to provide the necessary training of physicians, chemists, mechanical engineers and other professional personnel in order to cope with the industrial hygiene problem in the national emergency.

Third, the whole field of activity that is known as public health will expand beyond any previous concept. Connecticut is fortunate in having efficient and well integrated public health authorities and their abilities and resources will be called upon to extend and strengthen their control of water and food supplies, the prevention of epidemics and the supervision of areas in which troop concentrations are located. But these official health agencies will not be adequate without the thoughtful and willing help of private physicians everywhere.

These are the things that will come first and while they are being arranged in an orderly pattern, wise people will look grimly ahead to the possibility of invasion and the resulting chaotic disturbance of the civil organization upon which we rely. Connecticut and adjacent states are in an exposed and vulnerable position and would surely become a target area for an invader. Plans for the evacuation of the civilian population should be contemplated and paper organization made for the care of casualties among civilians. We view with pride and security our well organized and splendidly equipped hospitals which we are confident could carry almost any emergency load if they were emptied of their peace time population, but another picture would present itself if some of those hospitals were no longer operable and their abandonment forced. These are not happy circumstances to contemplate, but if they may come, there is much to be gained from their thoughtful anticipation.

There is no time for apathy or stubborn adherence to a wishful remoteness. Physicians, perhaps more than any others, detest war because it is wholly contrary to their creed of charity and tolerance. But we also love liberty and independence and if our democracy is to stand, we, of our own free will, must now do our part with calm deliberation.

From the Executive Director's Office

CALL
SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1990 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, 275 Research Parkway, Meriden. The meeting will commence at 12:30 p.m. on Wednesday, November 28, and will continue until all business has been concluded.

11:30	Registration and Luncheon
12:30	Call to Order

Mehdi S. Eslami, M.D., President
Kenneth M. Robbins, M.D., Speaker of the House
Marjorie G. Petro, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member or Postgraduate Physician Member of The Society, in compliance with the following provisions.

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

PROPOSED AMENDMENT TO THE BYLAWS

The following proposed amendment to the Bylaws was presented to the House of Delegates on May 9, 1990 and was tabled for consideration and action at the next regular meeting of the House of Delegates.

In accordance with the Bylaws, this amendment is being published in *Connecticut Medicine* "on one or more occasions prior to the next meeting—at which meeting the amendment shall be taken off the table and acted upon by the House of Delegates."

SUBJECT: DELIQUENCY

PURPOSE: TO REMOVE PENALTY FOR DELINQUENCY

The Council recommends the following changes: Article XII, DUES: Section 4, Delinquency (Deletion in brackets and capitals.) Par. 1 - An Active Member is delinquent if his dues are not paid by April 30th of the year for which dues are prescribed and shall forfeit his Active Membership in the Society if he fails to pay the delinquent dues within thirty days after notice of his delinquency has been mailed to his last known address by the Executive Director of the Society. (ACTIVE MEMBERS OF THE SOCIETY WHO HAVE BEEN DROPPED FROM THE ACTIVE MEMBERSHIP ROLL FOR NONPAYMENT OF DUES CANNOT BE REINSTATED UNTIL SUCH INDEBTEDNESS HAS BEEN DISCHARGED, BUT SUCH INDEBTEDNESS SHALL APPLY ONLY TO THE ONE FISCAL YEAR OF DELINQUENCY.)

NEW MEMBERS

Members of the Connecticut State Medical Society join in welcoming these new members into a progressive state medical organization. CSMS is dedicated to promoting the science and art of medicine, the protection of the public health, and the betterment of the medical profession. Each new menber is encouraged to join with other CSMS members at both the county and state levels in achieving these goals.

FAIRFIELD COUNTY

Carolyn B. Becker, Danbury
Robin Berger, Trumbull
Mary E. Betit, Stamford
Denis A. Bouboulis, Brookfield
Catherine J. Campbell, Newtown
Deborah A. Caserta-Brunson, Bridgeport
Thomas V. Cigno, Ridgefield
Charles P. Cochran, Jr., Norwalk
James G. Cunningham, Greenwich
Joseph D'Agosto, Stamford
James W. Depuy, Danbury
Amanda B. Dill, Danbury
Robert D. Dresdner, Westport
Vito Ferrucci, Stamford
James W. Finnerty, Bethel
Frank B. Florence, Bridgeport
Ronald A. Giannotto, Stamford
David B. Gropper, Danbury
Stewart C. Gross, Bridgeport
JoEllen Habas, Greenwich
Constance Hiller, Brookfield
Pamela B. Hoffman, Bridgeport
Silvia Knoploch, Westport
Elin S. Kropp, Stamford
Pratap S. Kurra, Norwalk
Sarojini Kurra, Brookfield
Laura K. Lasley, Danbury
Kathleen A. LaVorgna, Westport
Robert M. Lincer, Stamford
Mark Litchman, Greenwich
Laurence S. Lorefice, Old Greenwich
Kenneth R. Mauer, Westport
Ellen S. Naidorf, Stamford
Manh D. Nguyen, Westport
Cynthia T. Portal, New Canaan
Kishore N. Ranade, Ridgefield
Stephen G. Rosen, Stamford
Martin Ross, Norwalk
Claude D. Simon, Milford
Myra L. Skluth, Norwalk
John A. Spera, Brookfield
Mark C. Steckel, Bridgeport
Peter L. Steenbergen, Easton
Eva K. Szaniawski, Stamford
Emily E. Tirpaeck-Blair, Bridgeport
Stephen J. Urciuoli, Bridgeport
Stuart A. Waltzman, Weston
Larry S. Wasser, Danbury
Eric L. Wasserman, Stamford
Thomas P. Whelan, Danbury
Peter B. Wittstein, Stratford
Dino G. Zacharakos, Norwalk
David K. Zucker, Fairfield

HARTFORD COUNTY

Dennis Balgowan, New Britain
Harold E. Beam, Vernon
Chris W. Bentley, Marlborough
Renu Bhateja, Bristol
Michel D. Bourque, Hartford
Amy S. Breakstone, Bristol
Philip J. Brunquell, Newington
David B. Bybee, New Britain
Ritchard G. Cable, Farmington
Kenneth F. Casey, Farmington
Raymond J. Chagnon, Hartford
Helen L. Chisholm, New Britain
William Cristo, Jr., Lenox
Steven S. Crohn, Enfield
Edward B. Cronin, Hartford
Jeffrey S. Davies, West Hartford
Robert S. Dicks, Hartford
Roberta A. Dilego, Hartford
Robert M. Dodenhoff, New Britain
Nicholas B. Formica, New Britain
James W. Freston, Farmington
Matthew Friedman, South Windsor
Sheryl G. Gabram, Hartford
Sobhy L. Ghabrial, Manchester
Stephen N. Grimaldi, Glastonbury
Pamela C. Griswold, West Hartford
Michael J. Jimenez, West Hartford
Thomas G. Jones, Farmington
Joseph C. Kambe, New Britain
Timothy W. Kelly, Hartford
Parveen Khanna, Manchester
A. E. H. Knox, Bristol
Joseph M. Langner, Southington
Anthony A. Luciano, Farmington
Joseph E. Marakovits, Bristol
John W. Mc Carrick, Manchester
Jose P. Mendoza, Bristol

C. G. Mesologites, West Hartford
George D. Mitchell, Hartford
Stacy R. Nerenstone, Hartford
Wayne C. Paulekas, Wethersfield
Anne M. Reiher, Bloomfield
Stephen G. ReMine, Farmington
Charles R. Robinson, Bristol
Edward M. Rosenblatt, Manchester
Steven T. Ruby, Farmington
Allan H. Schwartz, Glastonbury
Kevin P. Shea, Farmington
James D. Sidman, Farmington
Mark W. Sohner, Bristol
Jeffrey D. Spiro, Farmington
Bruce E. Stein, Manchester
Neil D. Stein, West Hartford
William H. Stephan, III, Bristol
Bollepalli Subbarao, New Britain
Teresa M. Szajda, Farmington
Eriko Tarantino, South Windsor
James I. Tauber, Rocky Hill
Robert R. Toscano, Simsbury
Roberto Troncoso, Hartford
Peter B. Wade, Hartford
Thomas G. Ward, Bristol
David L. Wasley, Terryville
Donald S. Weinberg, Cromwell
Renata Weissberg, Newington
Sue K. Wink, Hartford
Dana Wiseman, Glastonbury
Aris D. Yannopoulos, Bloomfield
Thomas J. Yasuda, Hartford
Neil S. Yeston, Hartford

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Renee M. Celso, Winsted
Paul A. Cooper, Canton

MIDDLESEX COUNTY

Michael Klein, Middletown
John Notar-Francesco, Southington
Sandra Wechsler, Middletown

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Anita L. Bourque, Waterbury
Johnnie Y. Bradley, Simsbury
Edgar Catala, Bristol
Phillip S. Dickey, New Haven
Claudia S. Dinan, New Haven
Charles A. Guglin, Milford
Jay E. Hellreich, Meriden
Oscar F. Hills, New Haven
Regina O. Hillsman, Watertown
Lori R. Hoch, Milford
Steven Kahn, Meriden
Robert I. Leventhal, Waterbury
Joseph M. Mc Namara, Guilford
Jeffrey A. Orell, New Haven
Wen-Jen H. Poo, North Haven
Sujata Prasad, New Haven
Camille N. Raad, Wolcott
David I. Riccio, East Haven
Joan O. Richter, Madison
Mary E. Swaykus, Branford
Gary F. Tansino, Meriden
Jose R. Villaluz, Waterbury

NEW LONDON COUNTY

Bruce E. Bailey, Canterbury
Barbara J. Bath, Plainfield
H. John Bodin, Norwich
Louis V. Buckley, New London
Nancy K. Cusmano, Norwich
Terrence A. Doherty, Old Lyme
Amr El-Badry, North Stonington
Anil Guatam, New London
John J. Giacchetto, Norwich
Steven B. Goldblatt, Colchester
Caren R. Goodman, New London
Calypso Gounti, New London
Michael D. Hein, Norwich
Valerie I'Anson, Richmond
Salim S. Isa, Norwich
Suzanne J. Klekotka, Waterford
Franklin F. Leddy, Mystic
Patrice M. Marchand, Norwich
Steven L. Powell, Norwich
Gaylord H. Rockwell, New London
Jean A. Siebenaler, Old Lyme
Patricia A. Stuart, Norwich

TOLLAND COUNTY

Lenora S. Williams, Ellington

WINDHAM COUNTY

Garfield W. Danenhower, Putnam
Michael D. Fine, Danielson
Carol S. Levitt, Danielson
Ramsey Tarabishy, Putnam

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a free service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to Physician Placement Service, Connecticut State Medical Society, 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

EMERGENCY MEDICINE

Middlesex Memorial Hospital, a 240-bed community hospital with a Residency Program in Family Practice, is recruiting a full-time medical director, and one full-time staff physician, to staff our second free-standing emergency facility owned and operated by the Hospital as a division of Middlesex Memorial's Department of Emergency Service. The facility has been approved by the State's Commission on Hospitals and Health Care to operate 12 hours a day, seven days a week, and will receive ambulances and be an integral part of the community's EMS system. It is located in a highly desirable and rapidly growing residential community approximately 20 miles from Hartford and Middletown. Physicians will be credentialled as members of the Emergency Department at Middlesex, and will have the opportunity to work extra shifts in the Emergency Department if desired. We would prefer physicians with emergency department experience and board certification or eligibility in EM, IM, or FP. The medical director will have on-site responsibility for policy development and implementation, staff, QA, etc. Highly competitive salary, plus incentive. A complete range of outstanding hospital benefits. CV's to W. Gordon Van Nes, M.D., FACEP, Chairman, Department of Emergency Services, Middlesex Memorial Hospital, Middletown, CT 06457. Telephone: 344-6691. (July 1990)

Full-time and part-time for urgent care center in Fairfield, CT; affiliated with community teaching hospital. Hospital privileges and teaching opportunities encouraged. Nice work setting, pleasant staff and well-educated and motivated patient population. General internal medicine, family practice or emergency medicine physicians preferred. Competitive salary, excellent benefits. Please contact John Hammel, M.D., 1055 Post Rd., Fairfield, CT 06430. (203) 259-3440.

GENERAL PRACTICE/INTERNAL MEDICINE

Physician needed for general practice or internal medicine. Location: Hilliard Bldg., Manchester, CT. Phone 1-649-4838 or 1-226-4456.

INTERNAL MEDICINE

Grove Hill Medical Center—BC/BE internist to join satellite office of 56-physician multispecialty group in Central Connecticut. Experience in women's health care preferred. University-affiliated hospital and teaching opportunities. Position available June 1991, affords opportunity for association within one of the East Coast's oldest and most respected group practices, generous salary and benefits, and earned partnership status. Interested candidates should forward CV to: Kenneth T. Johnson, M.D., CEO, Grove Hill Medical Center, 300 Kensington Ave., New Britain, CT 06051.

Grove Hill Medical Center—BC/BE internist to join 56-physician multispecialty group in Central Connecticut. University-affiliated teaching program. Position available June 1991, affords opportunity for association within one of the East Coast's oldest and most respected group practices, generous salary and benefits, and earned partnership status. Interested candidates should forward CV to: Kenneth T. Johnson, M.D., CEO, 300 Kensington Ave., New Britain, CT 06051.

Associate pulmonary specialist sought to work with three established, board certified pulmonologists. Opportunity to work exclusively in pulmonary medicine in Meriden-Wallingford-Southington Connecticut areas in community hospitals. Additional opportunities available in nearby facilities. Please contact Richard Smith, M.D., (203) 238-8235.

BC/BE Internist for private practice with coverage and guaranteed income sponsored by expanding full service hospital three hours from NYC and Boston in attractive four season community. Send CV to: Yvonne Nakashian, 115 Spencer St., Winsted, CT 06098.

OBSTETRICS & GYNECOLOGY

Southwest Connecticut. Excellent opportunity for female/male, BC/BE, Ob/Gyns. Well established progressive practice needs a new partner to replace retiring physician. We do in-office ultrasounds, colposcopy and fetal monitoring. Located across from hospital. Send CV to: Tim Sharpe, M.D., 284 Broad St., Milford, CT 06460.

PART-TIME

Part-time (15 hours/week) physician sought for Student Health Services at Southern Connecticut State University in New Haven. Willing to do some gyn work (not surgery) desired but not essential. Hours: 2:00 P.M.-5:00 P.M., Monday through Friday. Reply to (203) 397-4457.

M.D. Health Plan seeks a physician to serve as part-time Assistant Medical Director. The qualified candidate should be an active practicing physician with two years experience in application of quality assurance and utilization management techniques in a managed care environment preferably HMO. Exceptional written and communication skills are a must. Salary is negotiable. Interested candidates should send a resume to: D.A. Hayward, President & CEO; M.D. Health Plan, 6 Devine St., North Haven, CT 06473.

The Connecticut State Department of Education's Division of Rehabilitation Services is currently recruiting for contractual part-time Medical Consultants as follows: District Medical Consultants ($45.00/hr) and District Psychiatric Consultants ($45.00/hr). For further information, interested candidates should contact and/or submit a letter of application, vitae and copy of license to: Albert J. Sidlovsky, Jr., Consultant, Medical Relations, Division of Rehabilitation Services, Bureau of Organizational Support, 10 Griffin Road North, Windsor, CT 06095. Tel: (203) 298-2036.

PART-TIME (Cont.)

Full-time and part-time for urgent care center in Fairfield, CT; affiliated with community teaching hospital. Hospital privileges and teaching opportunities encouraged. Nice work setting, pleasant staff and well-educated and motivated patient population. General internal medicine, family practice or emergency medicine physicians preferred. Competitive salary, excellent benefits. Please contact John Hammel, M.D., 1055 Post Rd., Fairfield, CT 06430. (203) 259-3440.

PEDIATRICS

BC/BE pediatrician to join two young pediatricians in growing, congenial practice in New Haven County. Full or part-time, beginning July 1991 or sooner. Affiliated with major teaching hospital. Please reply to Dr. Ellen Wolfson, 50 South Main St., Wallingford, CT 06492.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

GENERAL SURGERY

Jul. '91. Age 33. Nat'l bds. AB elig. MD, SUNY at Stony Brook, Stony Brook, NY; Int., Booth Memorial Medical Center, Flushing NY; Res., Huron Road Hospital, Cleveland, OH. Prefers group or assoc. type practice in a medium to large-sized community. Write, Donna Vecchione, M.D., 27700 Bishop Park Dr., #402S, Willoughby Hills, OH 44092.

INTERNAL MEDICINE

July '91. Age 32. Nat'l bds. AB cert. MD, Autonomus University of Guadalajara, Guadalajara, Jalisco; Int., Res., and Fellowship, College of Medicine & Dentistry of New Jersey—New Jersey Medical School, Newark. Prefers group or associate type practice. Write, Joseph L. Ianello, M.D., 72 Newark Ave., Apt. #5, Belleville, NJ 07109.

Aug. '90. Age 57. Licensed in Connecticut. Nat'l bds. AB cert. M.D., Boston University School of Medicine, Boston, MA; Int. and Res., Hartford Hospital, Hartford, CT. Prefers institutional or industrial type practice. JD Degree, New England College School of Law. Write, Charles A. Gundersen, M.D., 301 Tall Timbers Rd., Glastonbury, CT 06033.

Nephrology. July '90. Age 35. Licensed in Connecticut. FLEX. AB elig. M.D., Institute of Medicine & Pharmacy, Bucharest, Romania; Int. and Res., St. Barnabas Medical Center, Livingston, NJ; Fellowship, University of Medicine & Dentistry, New Jersey Medical School, Newark, NJ (Nephrology and Renal Pathology). Prefers group, assoc., institutional or solo practice. Write, Guy D. Sbar, M.D., 125 Elm St., Third Floor, Westfield, NJ 07090.

INTERNAL MEDICINE/FAMILY PRACTICE

Immediately available. Age 31. Licensed in Connecticut. MD, Universidad del Noreste, Tampico, Mexico; Fifth Pathway, (NYU) Booth Memorial Medical Center, Flushing, NY; Int. and Res., Flushing Hospital and Medical Center, Flushing. Prefers ambulatory care/office based type practice in a medium-sized community. Write, William M. DiFederico, M.D., 324 Sunnybank Ave., Stratford, CT 06497.

OPHTHALMOLOGY

Sept. '90. Age 37. Licensed in Connecticut. Nat'l bds. MD, University of California, San Francisco, CA; Int. Kaiser Foundation Hospital, San Francisco (IM); Res., University of California, San Francisco (OPHTH); Fellowship, Massachusetts Eye & Ear Informary, Boston, MA (OPHTH). Write, CSMS, c/o MP/OPHTH.

PSYCHIATRY

Immediately available. Age 49. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD, Osmania Medical College, Osmania University, Hyderabad, Andhra, India; Int., Osmania General Hospital, Hyderabad; Res., Manchester University, England; Fellowship, William S. Hall Institute of Psychiatry, Columbia, SC. Prefers part-time positions. Naimetulla A. Syed, M.D., Box 5525, Fairfield Hills Hospital, Newtown, CT 06470.

PAID CLASSIFIED ADVERTISING

All paid classified advertising orders, correspondence and payments should be directed to : CONNECTICUT MEDICINE, Classified Department, 160 St. Ronan St., New Haven, CT 06511, Tel. (203) 865-0587. The classified rates are as follows: $60.00 for 25 words or less; plus $1.00 for each additional word. For confidential answers, the cost is $3.00 per insertion, sent in care of CONNECTICUT MEDICINE. Ad copy, with payment, must be received no later than the first day of the month preceding month of issue.

MEDICAL OFFICE(S) to sublet. Rockville and Somer, CT. Minutes from local area hospitals. Fully furnished. Ideal for satellite office or new practice. Call 763-4051.

MAINE—PEDIATRICIAN. Assume busy practice in a charming southern Maine community 35 miles from two metro areas. Minutes to the Atlantic Ocean, fresh water lakes, and major ski areas. Attractive salary and benefits including a staffed and equipped office on the hospital campus. Contact in confidence: Cheryl Broderick, E.G. Todd (1-800-762-9213).

REAL ESTATE ADVERTISEMENT. Monroe, CT: Gracious custom 4 B/R $2\frac{1}{2}$ Bath Colonial on 3+ acres. Custom cherry panel cabinets and ceramic tile kitchen and baths. Excellent location for professional—owner occupied. Asking $284,900. For appointment call/owner (203) 268-8057.

TO SHARE: Fully equipped medical office in Stamford, CT. Separate office. Share exam rooms, waiting area, X-ray and equipment. Available immediately. Reasonable. Call 329-8457.

PHYSICIAN'S OFFICE/HOME COMBINATION. Retiring physician selling unique property for physician or other professional. Prime residential location in Trumball, Fairfield County, CT. Special permit was obtained for this office/home structure. Easy access to all area hospitals. Call (203) 261-4111.

AIM HIGH. Today's Air Force has special opportunities for qualified physicians. As an Air Force physician you can pursue medical excellence as well as enjoy 30 days vacation with pay per year and a non-contributing retirement plan if you qualify. Discover how special an Air Force physician can be. Call: USAF HEALTH PROFESSIONS, 1-800-423-USAF. AIR FORCE.

ATTENTION CONNECTICUT STATE MEDICAL SOCIETY MEMBERS

A PHYSICIAN'S GUIDE TO THE NATIONAL PRACTITIONER DATA BANK

FOUNDED IN 1792

An American Medical Association publication reprinted for the convenience of our membership.

If you should have any question concerning the National Practitioner Data Bank,
call the Connecticut State Medical Society at 865-0587
and ask for Government Relations or Special Services.

1990
(Remove and save for reference)

Informing Physicians About the National Practitioner Data Bank

In enacting the Health Care Quality Improvement Act (HCQIA) of 1989, Title IV of Public Law 99-660, Congress found: (1) that there is an increasing occurrence of medical malpractice and the need to improve the quality of medical care; (2) that the threat of liability for money damages, particularly treble damages under federal antitrust law, unreasonably discourages physicians from participating in peer review; and (3) that there is need to provide incentive and protection for physicians engaging in effective peer review.

The Act is intended to protect the public from incompetent physicians by: (1) providing immunity from liability for damages resulting from good faith peer review activities; and (2) establishing a central data bank that serves as a nationwide repository for information related to professional conduct and competence, licensure status, and the malpractice claims experience of physicians.

After four years of discussion and long delays, the National Practitioner Data Bank opened in September 1990.

This booklet is provided free to AMA member physicians and is being reprinted by CSMS to help develop better understanding of and compliance with the new reporting requirements. The booklet describes the Data Bank and provides clarification of reporting and querying (Title IV) requirements of importance to the physician. Information on how a physician may dispute information reported to the Data Bank is included, along with a series of questions and answers about the Bank's operations.

How Requirements Affect Physicians

This section briefly describes the required methods of reporting and requesting information from the Data Bank that are of concern to the physician. Data Bank requirements did not become effective until the Data Bank became operational September 1, 1990 and no retroactive reporting is required.

Required Reporting

The physician should be aware that there are four types of actions that must be reported to the Data Bank:

1. *Medical Malpractice Payments*

Each person or entity, including an insurance company, which makes a payment on behalf of any licensed physician as the result of a written claim or a judgment *must* report information to the Data Bank and State Board of Medical Examiners. If a physician makes a payment to a patient as a result of a claim or judgment, the physician is responsible for filing a report with the Data Bank and state medical board.

Persons or entities must simultaneously submit information to the Data Bank and to the state licensing board within 30 days from the date payment is made. Any person or entity that fails to report required information on a payment is subject to a civil money penalty of up to $10,000 for each such payment involved.

2. *Licensure Actions Taken by Boards*

Each Board of Medical Examiners *must* report to the Data Bank any disciplinary action based on reasons relating to a physician's professional competence or professional conduct.

The Board must submit information within 30 days from the date the licensure action was taken.

3. *Clinical Privilege Actions*

Hospitals and other health care entities *must* report to their State Board of Medical Examiners when certain adverse actions are taken against a physician's clinical privileges.

Each hospital or health care entity must report the following clinical privilege actions:

- Any professional review action, based on the physician's professional competence or conduct which affects or could affect adversely the health or welfare of a patient(s), that results in denial, revocation, suspension, limitation, or reduction of the clinical privileges of a physician for a period longer than 30 days.
- Acceptance of the surrender or restriction of clinical privileges by a physician while under investigation by the hospital or health care entity relating to possible incompetence or improper professional conduct, or in return for not conducting such an investigation or proceeding.

The hospital or entity must report an adverse clinical privilege action to the State Board of Medical Examiners within 15 days from the date the adverse action was taken by the governing body. The State Board must submit the information received from the hospital to the Data Bank within 15 days from the date of receipt of the information.

4. *Society Membership Actions*

Professional societies of physicians which engage in professional review activity through a formal peer review process for the purpose of furthering quality health care *must* report adverse membership actions to the Data Bank.

Querying Information

Every physician can periodically request a copy of his or her Data Bank file, and this information will be sent at no charge to the physician. Note that if the physician has never received notification of a report being filed, then no adverse information will be on file concerning him or her in the Data Bank.

- Each hospital *must* request information from the Data Bank when a physician applies for medical staff membership or clinical privileges, and every two years while the physician is on its medical staff or has clinical privileges. Hospitals may also request information from the Data Bank at any time they deem it necessary.
- The other authorized entities that may request information from the Data Bank are state licensing boards, health care entities that provide health care services and have a formal peer review process, and professional societies that have a formal peer review process.
- A plaintiff's attorney or *pro se* plaintiff who has filed a professional liability action or claim against a hospital and specific physician(s) may query the Data Bank for information regarding a specific practitioner who is named in the action against the hospital. However, this is only when there is evidence that the hospital failed to make a mandatory query from the Data Bank regarding the practitioner(s) named in the action or claim. Further, the information obtained from the Data Bank on the practitioner can only be used with respect to the action or claim against the hospital, and not against the practitioner.

The fee for each inquiry to the Data Bank is $2.00.

Disputing Data Bank Information

When a physician believes that the information in a report filed with the Data Bank contains inaccurate or incomplete information, he or she is to attempt to resolve the problem through discussion with the entity which reported the information.

The physician has 60 days (from the date the Data Bank processed the report) to dispute the accuracy of information contained in the report.

In order to dispute the information, the physician must:

- Sign, in the appropriate space, the Practitioner Notification Document received from the Data Bank to inform the Secretary of Health and Human Services of the physician's disagreement with the report, and request that the report be entered into a "disputed" status.

- Describe in writing on the Notification Document the reason for the disagreement with the report (e.g., incorrect or incomplete information).
- Return the Notification Document to the National Practitioner Data Bank, P.O. Box 6048, Camarillo, CA 93011-6048. If the physician wishes to send the report by certified registered mail, address it to: National Practitioner Data Bank, 5151 Camino Ruiz, Mail Drop E-102, Camarillo, CA 93012.
- Inform the reporting entity in writing of the disagreement with the report and the basis for it.
- Attempt to discuss the situation with the reporting entity to resolve the dispute.

If the Data Bank determines that the reporting entity has already corrected or voided the disputed report, the physician will be informed or the results. An Improper Dispute Notification form will be sent to the physician by the Data Bank. The information contained in the disputed report is then corrected or deleted from the physician's file to avoid disclosure of erroneous information.

If the physician still contests the accuracy of the corrected report, he or she may initiate a new dispute. If the disputed report is not corrected or voided by the reporting entity, the dispute process can take one of several courses:

- A notation is placed in the file indicating the information is being disputed by the named physician, and all queries who had previously requested and received the information are simultaneously notified. The Data Bank also acknowledges receipt of the dispute to the physician.
- If the reporting entity then corrects or voids the disputed report, the Data Bank confirms receipt of the information by sending a Report Verification Document to the reporting entity. When needed, a Response to Disputed Notification document will be sent to all queriers who received the original report. The physician will also be notified of all actions.
- If the reporting entity does not revise the reported information, the Secretary of Health and Human Services will, upon request, review the written information submitted by both the physician and the reporting entity. After review, the Secretary will conclude whether the information is either incorrect or accurate. The Secretary will not determine the merits of the claim nor the appropriateness of the professional review action in the report.
- If the Secretary determines that the report is incorrect, the information will be corrected. If it is determined that the information should never have been reported, the report will be voided. If it is determined that the information is accurate, the Secretary will include an explanation of the basis for the decision in the report.
- The physician will be permitted to place a brief statement in the Data Bank file describing the disagreement. All queries who request and receive disputed information, the subject physician, and the reporting entity will be informed of the resolution of the dispute.

Confidentiality of Data Bank Files

The information contained in the Data Bank is confidential and intended for authorized entities only. Any person who violates the confidentially provisions shall be subject to a civil penalty of up to $10,000 for each violation. The Office of Inspector General is responsible for enforcing the confidentiality provisions of the HCQIA.

Questions and Answers About the Data Bank

The following questions and answers are those most frequently asked about the National Practitioner Data Bank.

If a malpractice payment is made on behalf of a clinic or hospital, will the names of all member practitioners be reported?

Medical malpractice payments made solely on behalf of a clinic or hospital, as contrasted with a person, are not reportable to the Data Bank. The payment must be made for the benefit of a physician, dentist or other licensed or otherwise authorized health care practitioner to be reported to the Data Bank.

How is a physician reported when he or she is named in an action based on the services of a health care practitioner under his or her supervision?

If a payment is made for the benefit of a physician for a claim which arose from the services of a subordinate, the physician would be reported using the same malpractice claim description code as was used for the subordinate. The reporting entity may provide further explanation of the circumstances surrounding the complaint or claim in the narrative description.

If a physician waives a bill for services to a patient following informal mediation of a complaint, must the physician report it as a medical malpractice payment?

The waiver of a debt or bill would not be reportable event. An exchange of money must be involved.

If a stipulation of settlement or court order requires that its terms remain confidential, how does a malpractice insurer report the payment to the Data Bank without violating the settlement agreement or court order?

The stipulation that the terms of a settlement or judgment remain confidential does not excuse an entity making a payment for the benefit of the physician from the statutory requirements to report that payment to the Data Bank. Failure to do so will subject the entity to the $10,000 fine provided in the Act.

When must an adverse action on clinical privileges be filed?

Adverse actions on clinical privileges must be reported to the State Medical Board within 15 days after the adverse action is made final by the entity's authorized official or by the entity's governing board.

Are adverse actions on clinical privileges reportable prior to hearings?

As stated above, the action is not reportable until it is made final by the health care entity. If the health care entity followed the procedural requirements of Part A of the "Health Care Quality Improvement Act" (HCQIA) in order to obtain immunity protection for its action, it would have given the physician notice and an opportunity for a hearing or other procedures which were fair to the physician under the circumstances.

Are adverse action on clinical privileges reportable prior to appeals?

Adverse actions on clinical privileges are not reportable until the are made final by the health care entity. If an internal, administrative appeal preceding final action by the entity is provided for the health care entity's bylaws, then the action is not reportable until the conclusion of this appeal. However, in the event an adverse action which has been reported is subsequently modified or vacated after an appeal by the physician, the health care entity would be responsible for filing a revised report with the Data Bank.

Are investigations reportable if they do not reach a conclusion?

Investigations, per se, are not reportable events. However, the acceptance of the surrender of clinical privileges or any restriction of such privileges while the physician is either under investigation or to avoid an investigation by the health care entity relating to possible incompetence or improper professional conduct must be reported to the Data Bank.

If a physician "plea bargains" and is allowed to resign from a hospital staff during an investigation, is it reported?

Yes. Acceptance of the surrender of clinical privileges while the physician is under investigation by the health care entity relating to possible incompetence or improper professional conduct must be reported to the Data Bank.

Does entrance into a drug, alcohol or psychiatric rehabilitation program for 30 days or more require reporting to the Data Bank if privileges are suspended?

Voluntary enrollment into a drug, alcohol or psychiatric rehabilitation program does not in itself constitute a reportable action. Suspension of clinical privileges for more than 30 days as a result of a professional review action based upon professional competence or conduct is reportable.

If an initial application for clinical privileges is denied or the privileges granted are more limited than those requested, must this be reported to the Data Bank?

Yes, if the denial of an initial request for clinical privileges or the granting of privileges is more limited than those requested is based on a professional review action and relates to professional competence or conduct, it would be a reportable action.

Are there adverse actions that do not need to be reported to the Data Bank?

The following are examples of actions or recommendations by a hospital that are not based on the competence or professional conduct of a physician and, therefore, are not reportable to the Data Bank.

- Suspension of a physician's clinical privileges or medical staff membership due to a failure to complete medical records on time if the action has not compromised patient care.
- Denial of clinical privileges or medical staff membership because of the lack of need for the physician's services (i.e., closed medical staff or an exclusive contract).
- Suspension, denial or nonrenewal of clinical privileges or staff membership due to a failure to obtain or maintain a specified level of professional liability insurance.
- Denial of clinical or staff membership due to failure to comply with threshold eligibility requirements such as board certification, geographic requirements.
- Reduction or nonrenewal of privileges due to the physician's failure to meet new threshold requirements (i.e., board certification) or lapse in a requirement (i.e., Advanced Cardiac Life Support Certificate.)
- Reduction or nonrenewal of privileges due to the hospital's credentialing requirements, such as the physician's failure to admit a minimum number of patients to the hospital.

If a professional society denies membership to a physician, is that action reportable to the Data Bank?

The action must be reported to the Data Bank if the denial of membership was based on a professional review action conducted through a formal peer review process. The professional review action must also be based on an assessment of the physician's professional competence or conduct which affected or could affect the health and welfare of a patient or patients.

Will an entity that requests information on a practitioner be notified when a report on that practitioner is in the 30-day hold file?

Yes, after the Data Bank is operational, a mechanism will be developed and implemented to allow the Data Bank to alert a requesting entity that a report on a practitioner is in the 30-day hold file. A requesting entity will receive a Request for Information Disclosure—Requery document that can be used to requery the Data Bank on the practitioner after the report is eligible to be disclosed. A user fee will not be charged for the requery if it is submitted within 30 days following the report's release date, as noted in the document.

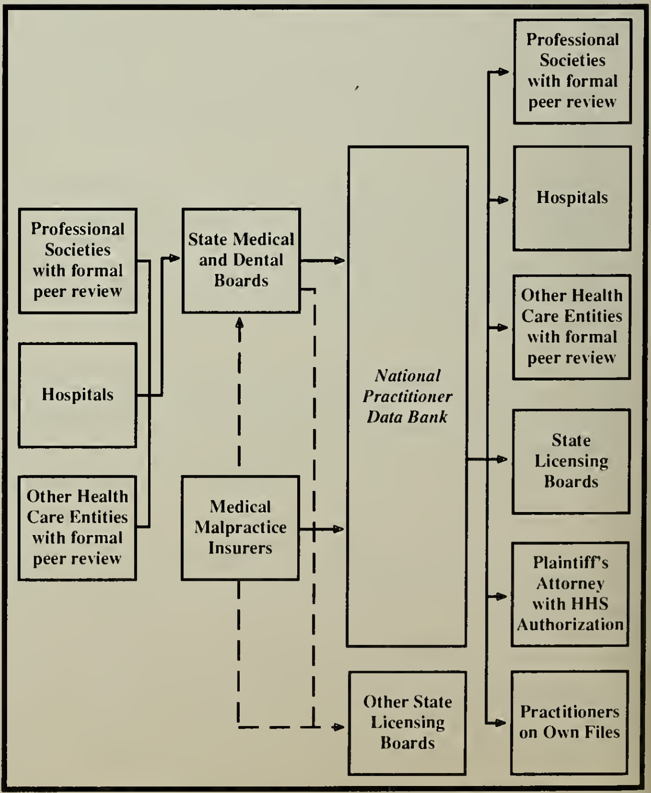
How will the Data Bank determine if query requests are legitimate?

Each eligible entity making a request for information from the Data Bank is required to have a Data Bank identification number. No information will be released until the entity is determined to be eligible to receive Data Bank information. The requesting entity must also certify in writing that it is eligible to request information from the Data Bank in accordance with the law and Title IV regulations. Self queries by physicians require a Data Bank identification number or a notarized statement certifying the identity of the physician. Accessing the Data Bank for fraudulent purposes is punishable by fines and imprisonment.

Is a hospital required to query the Data Bank on its medical interns and residents (house staff)?

No. Since house staff are trainees in structured programs of supervised graduate medical education and they are not granted clinical privileges in a formal sense nor are they generally members of the medical staff in a formal sense, there is no requirement placed upon the entity to query the Data Bank about them. Note, however, that reports must be submitted to the Data Bank when malpractice payments are made in their behalf or when adverse licensure actions are taken against them.

The American Medical Association has been able to resolve several concerns by working closely with key members of Congress to amend the Health Care Quality Improvement Act. In addition, the Association has been a forceful advocate for physician concerns both as a member of an advisory committee to the National Practitioner Data Bank and through the formal rule-making process. The Data Bank activity remains a high priority of the Association. The AMA supports the use of the information in the Data Bank to further quality health care, but is committed to limiting access to only those health care entities that engage in a professional review activity through a formal peer review process.


Professional Societies with formal peer review
Hospitals
Other Health Care Entities with formal peer review
State Medical and Dental Boards
Medical Malpractice Insurers
National Practitioner Data Bank
Other State Licensing Boards
Professional Societies with formal peer review
Hospitals
Other Health Care Entities with formal peer review
State Licensing Boards
Plaintiff's Attorney with HHS Authorization
Practitioners on Own Files

Beta-Carotene and Cancer Prevention: What Is the Evidence?

SUSAN TAYLOR MAYNE, PH.D.

ABSTRACT—A growing body of literature supports a possible role for beta-carotene in the prevention of human cancer. The most scientifically rigorous method for testing the hypothesis that beta-carotene has chemopreventive properties is with intervention trials, several of which are ongoing or soon to be initiated. Connecticut will be actively involved in three of these trials. This article reviews and critically evaluates the evidence supporting a role for beta-carotene in the prevention of human cancer, including animal studies, cell culture studies, epidemiologic studies, and intervention trials, and concludes with a brief description of chemoprevention research involving beta-carotene in Connecticut.

BETA-CAROTENE is one of a number of naturally occurring compounds called carotenoids. Carotenoids are generally highly colored, and are responsible for most of the red/orange/yellow colors observed in nature. Over 400 naturally occurring carotenoids have been identified, approximately 50 of which have vitamin A activity.[1] Carotenoids are widespread in plants and in photosynthetic bacteria, where it is thought that they serve two essential functions: as accessory pigments in photosynthesis, and in photoprotection.[2,3] These two functions are a consequence of the chemical structure of carotenoids, consisting of a series of conjugated double bonds (Figure 1), which allow the molecule to quench, or inactivate, singlet oxygen and free radicals.

Human beings routinely ingest a variety of different carotenoids, including those occurring naturally in foods and those added as food colorants. The function of carotenoids in humans is not entirely clear. Certain carotenoids called provitamin A carotenoids can be enzymatically converted in the intestinal mucosa to yield retinol (vitamin A). Retinol is required for vision, maintenance of differentiated epithelia, mucus secretion, and reproduction. Carotenoids also appear to show biological actions that are distinct from their function as vitamin A precursors.[4] For example, high-dose beta-carotene has been shown to be efficacious in the treatment of erythropoietic protoporphyria, a photosensitivity disorder.[5] Beta-carotene and other carotenoids have been shown to act as immunoenhancing agents in animal studies;[6] studies investigating immunoenhancing effects of carotenoids in humans are essentially unavailable.

Vitamin A, Beta-Carotene, and Carcinogenesis

Vitamin A is known to be required for cellular differentiation.[7] The pioneering work of Wolbach and Howe in 1925[8] showed that during vitamin A deficiency, proper differentiation of stem cells into mature epithelial cells failed to occur, resulting in abnormal differentiation. Cancer is essentially a disease of abnormal differentiation; therefore, it was hypothesized many years ago that vitamin A might protect against carcinogenesis by regulating cell differentiation. To date, numerous studies have demonstrated that vitamin A and derivatives of vitamin A, collectively referred to as retinoids, possess antitumor activity. The antineoplastic effects of retinoids have been comprehensively reviewed by others[9] and will not be discussed here.

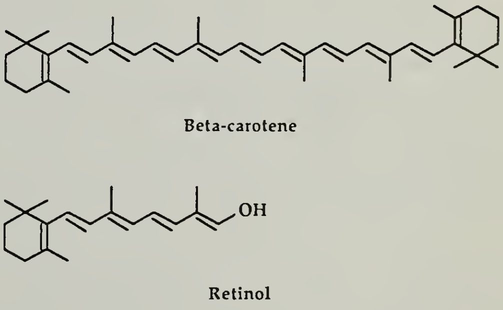


Figure 1
Structures of all-trans-beta-carotene and retinol.

Significant interest in the antitumor effects of carotenoids followed in the 1970s as an extension of the work with vitamin A. The recognition that the quenching of singlet oxygen by beta-carotene is an important protective mechanism in plants[10] suggested that this activity may also be important in humans. Additionally, carotenoids are related structurally to retinoids (Figure 1). Finally, provitamin A carotenoids, found in a wide variety of fruits and vegetables, account for more than half of the average

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American's intake of vitamin A. Beta-carotene, which has the greatest provitamin A activity of the carotenoids, has been investigated most thoroughly for possible antitumor properties and is the focus of this review.

Animal Studies

Much of the work concerning antitumor effects of beta-carotene on experimentally-induced carcinogenesis has been done with rodent skin tumor models. Epstein injected hairless mice with a solution of beta-carotene or a placebo three times per week for six months. Following one month of injections the mice were exposed to ultraviolet (UV) irradiation and tumor formation was monitored. Epstein observed that the resultant squamous cell carcinomas appeared later and grew more slowly in the beta-carotene-treated mice.[11] Dietary beta-carotene, administered before and during tumor induction, was shown to delay the onset of skin tumors induced in mice by either dimethylbenz[a]anthracene (DMBA)/croton oil application, UV light, or DMBA plus low doses of UV light.[12] Similar effects have also been reported by others.[13,14] Muto and Moriwaki[15] showed that dietary beta-carotene, administered after the formation of skin tumors in mice, caused a significant regression in tumor size, although a synthetic retinol analogue was more effective than beta-carotene. The protective effects of beta-carotene in a skin carcinogenesis model appear to be dose-dependent, as shown by Mathews-Roth and Krinsky.[16]

A series of reports also indicate that beta-carotene (topical, injected, or oral) can inhibit[17,18] and regress [19,20] DMBA-induced hamster buccal pouch carcinomas. For example, local injection of beta-carotene into the tumor-bearing buccal pouch resulted in a mean oral tumor burden of 42.7 cubic mm as opposed to 2,258 cubic mm in the sham-injected control group.[20] Others have investigated the effects of dietary beta-carotene on DMBA-induced salivary gland tumors in rats, and reported that tumor incidence was lower, although nonsignificantly, in the animals fed diets supplemented with beta-carotene.[21] Dietary beta-carotene administered during the initiation and promotion phases of carcinogenesis has been found to be protective against 1,2 - dimethylhydrazine (DMH) - induced colon tumors in mice;[22] however, others have failed to detect antitumor activity of dietary beta-carotene in gastrointestinal cancer models.[23,24] The latter report[24] should be interpreted with caution, however, since the high dose of DMH used in this experiment resulted in 100% colonic tumor incidence in both the placebo and beta-carotene-treated groups, potentially overwhelming any antitumor activity of beta-carotene. Finally, protective effects of dietary beta-carotene on a viral tumor model have been investigated. CBA/J mice inoculated with Moloney murine sarcoma virus had significantly fewer tumors with a greater latency period following the administration of supplemental beta-carotene before and/or after viral inoculation.[25]

Cell Culture Studies

Beta-carotene inhibited DMBA-induced transformation of murine mammary epithelial cells in vitro, regardless of whether the beta-carotene was added before or after the carcinogen.[26] No accumulation of retinol was observed in the mammary cells, suggesting that the inhibitory effect of beta-carotene was a result of some intrinsic property of the carotenoid molecule and was not mediated by conversion to retinol. Similarly, Pung and colleagues reported that beta-carotene inhibited methylcholanthrene or x-irradiation-induced transformation of 10T1/2 cells in culture.[27] Interestingly, inhibition was reversible upon removal of the carotenoids. Weitberg et al found that beta-carotene reduced the number of sister chromatid exchanges, an indication of genetic damage, in Chinese hamster ovary cells exposed to active oxygen species.[28] Other studies have also reported anticlastogenic effects of beta-carotene.[29,30]

Epidemiologic Studies

Many epidemiologic studies suggest that dietary intake of beta-carotene lowers the risk for several different types of cancer. These studies generally fall into one of the following design classes: prospective dietary studies, prospective serologic studies, or retrospective (case-control) studies.

In prospective dietary studies dietary information is obtained from a relatively large cohort of disease-free individuals who are then followed forward in time for subsequent development of disease. One of the first such studies relating carotenoid intake to cancer was that of Bjelke, who obtained dietary information from 8,278 Norwegian men and followed them for five years. Bjelke found that the relative risk for lung cancer was inversely associated with consumption of carotene-rich foods (carrots and green vegetables) at all levels of smoking.[31] In an exceptionally large study of 265,118 Japanese men and women, Hirayama found an inverse association between green-yellow vegetable consumption and mortality due to cancer of the lung, stomach, colon, and prostate.[32] In a highly publicized study of 1,954 men employed by Western Electric and followed for 19 years, Shekelle et al showed that intake of carotene was inversely related to the incidence of lung cancer at all levels of smoking, with men in the lowest quartile of intake having a seven-fold increase in risk relative to men in the highest quartile of carotene intake.[33] These and other[34] studies consistently show a dose-related decrease in risk for cancer, especially cancer of the lung, with consumption of carotene-rich foods. While supportive of the hypothesis that beta-carotene can reduce the risk for human cancer, these studies must be interpreted with caution since it is possible that some other factor found in carotene-rich vegetables is responsible for the observed protection, or that individuals with high vegetable intakes may avoid certain dietary or nondietary factors which increase risk for cancer.

In prospective serologic studies blood samples are collected from large numbers of healthy individuals, frozen, and stored. Study participants are followed for several years, and the samples from those who develop cancer are measured for the analytes of interest and compared to samples from individuals who remain free of cancer.

Prospective serum studies of beta-carotene and cancer indicate that sera obtained from individuals who later developed lung cancer are significantly lower in beta-carotene than sera obtained from matched controls.[35-37] While instability of beta-carotene during long-term storage of samples may be a potential problem in these studies, differential stability between blood obtained from lung cancer cases and controls is unlikely if samples are handled similarly. Additionally, Stahelin et al obtained sera from a large cohort, analyzed the samples immediately for nutrient content, then followed the cohort over time for cancer mortality. Consistent with the previous reports, beta-carotene was shown to be significantly lower in sera from individuals who later developed lung cancer, relative to controls (14.8 ug/dL vs 23.7 ug/dL, respectively; $p < 0.05$).[38]

A third group of epidemiologic studies that examine the association between beta-carotene and cancer are the retrospective, or case-control, studies. In these studies investigators question cancer patients (cases) and matched controls about their dietary habits in previous years. Alternatively, investigators may compare blood levels of beta-carotene in samples obtained from cancer patients and matched controls. Numerous case-control studies have found a significantly increased risk of certain cancers in persons with a relatively low intake of beta-carotene-rich foods (fruits and/or vegetables) or relatively low blood levels of beta-carotene. Protective effects have been reported most consistently for cancer of the lung,[39-48] cancers of the oral cavity, pharynx and larynx,[49-55] and cancer of the uterine cervix,[56-62] although protection at a variety of other tumor sites has been reported.[63-67] While these findings are promising, the results must be interpreted cautiously, since any observed protection could be due to (a) other nutrients or non-nutritive compounds found in beta-carotene-rich fruits and vegetables, (b) lifestyle habits including other dietary habits that may be associated with the consumption of fruit and vegetables, or (c) disease-induced alterations in blood levels of beta-carotene, or in the recollection of beta-carotene intake.

Intervention Studies

The epidemiologic, cell culture, and animal studies described in the previous sections strongly suggest that beta-carotene may play a role in human carcinogenesis. However, these studies all suffer from methodologic limitations that hinder their ability to demonstrate efficacy. The most scientifically rigorous method for determining whether an agent protects against human carcinogenesis is a randomized clinical trial, also known as an intervention trial, or chemoprevention trial. This design is feasible for examining chemopreventive activity of beta-carotene because (a) beta-carotene is commercially available and inexpensive, (b) high-dose beta-carotene has proven safe in its use in the treatment of photosensitivity disorders, and (c) beta-carotene is easily administered in supplemental form. These trials can be designed to assess the effects of supplemental beta-carotene on tumor markers, precancerous conditions, cancer incidence, or cancer mortality in a given study population. As of this writing, no randomized clinical trial which examines the effect of beta-carotene on cancer incidence or mortality has been completed; however, results from trials examining the effects of supplemental beta-carotene on intermediate endpoints of carcinogenesis have been reported.

Stich and coworkers have used the frequency of micronucleated cells in exfoliated oral mucosa to examine chemopreventive activity of beta-carotene. These micronuclei, which result mainly from chromatid or chromosome fragments, are used to provide a marker for genotoxic damage in tissues from which oral carcinomas develop.[68] Stich's group has consistently demonstrated that oral beta-carotene supplementation (180 mg/week) significantly decreases the frequency of micronucleated cells of high-risk populations.[68-70] The combination of beta-carotene plus retinol was more effective than either agent alone.[70] The authors attribute the success with the combination to the greater accumulation of beta-carotene in the oral mucosa with this treatment,[71] probably secondary to a decreased conversion of beta-carotene to retinol in the intestinal mucosa to meet vitamin A requirements. Supplemental beta-carotene was also shown to reverse leukoplakia, a premalignant lesion of the oral cavity, with a response rate of 82% in a recent U.S. study.[72] While this small study did not include a placebo-treated group for comparison, the response rate was impressive in that a similar leukoplakia trial using a different chemopreventive agent reported only a 10% response rate in the placebo-treated group.[73] The results from these beta-carotene trials using intermediate markers of carcinogenesis are promising; however, replication of the results with double-blinded trials seems warranted (references 68-70 do not specify if the study was blinded; reference 72 had only one treatment arm).

Table 1
NCI Cancer Prevention Trials Using Beta-Carotene

Cancer	*Study Population*	*Study Location*
All sites	U.S. Physicians	Boston
Lung	Smokers	Finland
	Smokers	Seattle
	Smokers	Pittsburgh
	Asbestos	Multicntr. incl. CT
	Asbestos	Tyler, TX
	Tin miners	China
Colon	Polyps	Hanover, NH
	Polyps	Chicago
Esophagus	Dysplasia	China
	General population	China
Skin	Albino	Tanzania
	Previous skin cancer	Hanover, NH
	Previous skin cancer	New York City
Oral/Larynx/Pharynx	Previous oral/larynx/ pharynx cancer	Connecticut

Adapted from "Cancer Prevention Research: Chemoprevention and Diet." Office of Cancer Communications, National Cancer Institute, February 1987.

A number of chemoprevention trials examining the effects of supplemental beta-carotene on human cancer are in progress in the United States, Finland, China, and Africa as summarized in Table 1. One study, the Physician's Health Study, was designed to answer two unrelated questions: (1) does aspirin lower the incidence of cardiovascular disease? and (2) does beta-carotene contribute to a decrease in total cancer incidence? The aspirin component of the study has been terminated,[74] but the beta-carotene component of the study continues. A number of Connecticut physicians are enrolled in this study, which involves a total of 23,000 U.S. male physicians. This is the only ongoing beta-carotene chemoprevention trial using all cancer sites as an endpoint; all other chemoprevention trials are tumor-specific.

In reviewing Table 1 it is apparent that beta-carotene chemoprevention of lung cancer in high-risk individuals is an active area of investigation. One such study is designed to determine if supplemental beta-carotene in combination with retinol reduces the incidence of lung cancer in men at increased risk for lung cancer because of occupational exposure to asbestos.[75] While this study is based at the Fred Hutchinson Cancer Research Center in Seattle, Washington, it is utilizing a multicenter design to aid in the recruitment of asbestos-exposed individuals, with one of the recruitment centers based in Connecticut. Dr. Mark Cullen, director of the Yale-New Haven Occupational Medicine Program, Dr. Martin Cherniack, director of Lawrence and Memorial Hospital's Occupational Health Center in New London, and Paula McManus, project manager, are directing the Connecticut recruitment site. This site will recruit workers from the Electric Boat Shipyard in Groton or other individuals who have had at least five years of high-grade asbestos exposure and who are current or former smokers. This study is in progress now, and will attempt to enroll 1,000 men from the Groton and New London area.

In addition to these two beta-carotene intervention trials that have Connecticut affiliations, one additional trial is based entirely in the state of Connecticut. The primary objective of this trial, which is funded by the National Cancer Institute, is to determine if supplemental beta-carotene inhibits the formation of second primary tumors and local recurrences in patients previously treated for early-stage cancer of the oral cavity, pharynx, or larynx. This study is being directed by Dr. Susan Taylor Mayne, Dr. W. Jarrard Goodwin, and Dr. Dwight T. Janerich, all of the Cancer Prevention Research Unit for Connecticut at Yale, and will recruit approximately 600 patients from Connecticut. Enrollment of subjects is expected to begin in mid-1990.

Conclusions

The evidence supporting a role for beta-carotene in the prevention of certain human cancers is based on epidemiologic studies, animal studies, cell culture studies, and intervention trials using intermediate markers of carcinogenesis, as reviewed in this article. Additionally, a chemopreventive effect of beta-carotene is biologically plausible based on the biological actions of beta-carotene, which have been extensively reviewed elsewhere.[4] The most scientifically rigorous method for determining whether beta-carotene protects against human carcinogenesis is the randomized clinical trial, several of which are ongoing or soon to be initiated. Connecticut will play an active role in three of these important investigations which have great potential to reduce cancer-related morbidity and mortality.

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A Case of L-Tryptophan-Induced Eosinophilia-Myalgia Resulting in Death

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ABSTRACT—A syndrome of eosinophilia and myalgias associated with the ingestion of L-tryptophan has recently been described. In a large majority of the cases reported to the Centers for Disease Control thus far, discontinuation of L-tryptophan consumption has resulted in complete resolution of symptoms. The author presents a case of L-tryptophan-induced eosinophilia-myalgia syndrome which was progressive despite discontinuation of the L-tryptophan. The condition was refractory to treatment and ultimately resulted in the death of the patient.

Introduction

A recently described syndrome of severe myalgias and peripheral eosinophilia has been associated with the oral consumption of L-tryptophan. Since the initial description of this syndrome by the New Mexico Department of Health and Environment,[1] the Centers for Disease Control has received over 1,250 case reports of L-tryptophan associated eosinophilia-myalgia syndrome (EMS) from state health departments.[2] Although symptoms resolve in the majority of patients after discontinuation of oral L-tryptophan, at least 13 of the cases reported to the CDC, as of 9 February 1990, have resulted in death despite discontinuation of L-tryptophan.[2] The author reports here a case of EMS with progressive muscle weakness resulting in respiratory failure and the subsequent death of the patient.

Case Report

A 69-year-old white female with a history of adult-onset diabetes mellitus and bipolar disorder presented in October 1989 with a complaint of two to three weeks of progressive weakness in the shoulders and pelvic region, myalgias, loss of appetite, and extreme dizziness during ambulation. She denied fever, chills, nausea, vomiting, cough, or shortness of breath. She had no recent travel history. Her medications were lithium, 600 mg in the morning and 300 mg at night; desipramine, 75 mg twice a day; micronase, 5 mg a day; flurazepam, 30 mg before bedtime; L-tryptophan (brand name-Solgar®), 10g at bedtime.

On admission she was afebrile; her blood pressure was 170/72 mm Hg with a pulse of 72 per minute in the supine position, and 90 (palp) mm Hg with a pulse of 100 per minute in the upright position. The skin was cool and dry and there was poor skin turgor. A macular rash was noted on the trunk and extremities. No adenopathy was detected. There was no jugular venous distention. The lungs were clear and the heart rate and rhythm were regular. The abdominal examination was unremarkable. On neurological examination the cranial nerves were grossly intact. Rotary nystagmus was noted on horizontal gaze in both directions. She could not raise her arms against gravity and had difficulty moving any of her muscles against resistance. She was unable to stand on her heels or her toes. Her sensory function was intact but the patient had markedly diminished proprioception. The deep tendon reflexes were brisk in all extremities and slightly greater in the upper extremities. She had a high-frequency tremor in both hands and an unsteady, wide-based gait.

The hemoglobin was 14.1 g/dL; hematocrit, 43%; white cell count, 13,700, with a differential of 58% neutrophils, 11% lymphocytes, 26% eosinophils, 4% monocytes, and 1% atypical lymphocytes; erythrocyte sedimentation rate was 37 mm/hr; creatinine kinase was 26 U/L, 21 U/L, and 26 U/L on three consecutive days; aldolase, 13 U/L (normal, 2-12); lactic dehydrogenase, 177 U/L; calcium, 8.7 mg/dL; total protein, 4.4 g/dL; albumin, 2.5 g/dL. The lithium level was 0.6 meq/L; free T4, 1.1 μg/mL; rheumatoid factor,<1:80; antinuclear antibody, <1:40; VDRL, nonreactive; C-reactive protein, 0.9 mg/dL; toxoplasma antibodies, negative; trichinella antibodies (IgG, IgM), negative. Urine culture was negative. Serum protein electrophoresis and complement levels were normal. A lumbar puncture to check for the Guillain-Barré syndrome revealed normal glucose and protein and no leukocytes, erythrocytes, or oligoclonal bands. There was no myelin basic protein detected in the spinal fluid. Electromyography showed no myopathy but did suggest a small degree

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of peripheral diabetic neuropathy. A punch biopsy of the skin showed edema of the papillary dermis, elastoid degeneration of dermal collagen, and scant perivascular lymphocytic infiltrate. Biopsy of the deltoid muscle revealed an inflammatory infiltrate without myofibrillar changes. Lymphocytes and histiocytes were present with rare plasma cells and eosinophils.

Because of the proximal weakness and in view of the results from muscle biopsy a presumptive diagnosis of polymyositis was made and the patient was given prednisone, 20 mg three times a day, and discharged from the hospital during the first week of November. She showed no improvement with steroid therapy. She was advised to discontinue her L-tryptophan after publication of a *New York Times* article in November 1989[3] on the possible association between L-tryptophan and an eosinophilia-myalgia syndrome.

The patient's symptoms progressed; therapy with metho-trexate, 15 mg/week, was begun but her clinical status deteriorated and she was readmitted to the hospital in December 1989 complaining of progressive weakness, shortness of breath, cachexia, and a nonproductive cough. Temperature was 38.6°C rectally, and blood pressure 156/90 mm Hg; pulse was 130 and respirations were 42. Examination revealed erythema of the hands and the periungual areas of all fingers; bilateral rales and rhonchi at the bases of the lungs; expiratory wheezes at the apices; and tachycardia. She was profoundly weak with severe muscle wasting, lethargy, and difficulty following commands. Her pupils were equal and round but poorly reactive to light. No muscle fasciculations were noted. The white cell count was 12,500 with 91% neutrophils, 7% lymphocytes, and no eosinophils. Serum aldolase was 5 U/L. Chest roentgenogram revealed increased interstitial markings and bilateral lower lobe fine infiltrates compatible with granulomas, but no acute disease process. Sputum cultures were negative. Urine culture grew *Pseudomonas aeruginosa*.

The patient was treated with broad spectrum antibiotics and intravenous steroids. Four days after admission she developed respiratory failure requiring intubation and ventilator support. Because the patient's condition continued to deteriorate, a 10-day course of plasmaphoresis was initiated with no change in clinical status. A peripheral nerve biopsy was performed. Minimal focal perivascular lymphocytic infiltrate was found. Another trial of plasmaphoresis was initiated, again without change in her clinical status. Ventilator support continued to be necessary because of severe respiratory muscle weakness. She was only able to generate a negative inspiratory force of 10-15 mm H_2O. After being on the ventilator for 36 days, weaning was eventually achieved. The patient experienced great difficulty clearing her secretions. She was discharged to home hospice with progressively deteriorating neurological status in January 1990. The patient died two days after discharge.

Discussion

L-tryptophan is an amino acid precursor of serotonin that has been sold as an over-the-counter dietary supplement for many years. Although it has been used as a popular remedy for insomnia and depression, studies of its efficacy as a sedative and as an antidepressant have been controversial.[4] Some investigators have even speculated that it might be neurotoxic in certain individuals.[5,6] For these reasons the FDA has never approved L-tryptophan as a medicinal drug.

Two recent case-control studies have provided evidence for an association between the ingestion of L-tryptophan and eosinophilia-myalgia syndrome (EMS).[7] Although a cause-and-effect relationship has yet to be definitively established, Flannery et al have reported a case of EMS in which eosinophilia and myalgias improved after withdrawal of L-tryptophan, but returned upon rechallenge with oral L-tryptophan.[8] Such evidence linking L-tryptophan to EMS has led the FDA to withdraw the substance from the market. Since L-tryptophan has been used for many years as a purported remedy for various ailments, the sudden association with a new clinical syndrome has led some to speculate that EMS may be caused by an impurity from the production process.[9] At present, no such impurities have been identified.

This patient presented with a striking eosinophilia and symptoms compatible with EMS. No infectious or neoplastic source for the eosinophilia was found. A typical perivascular inflammatory infiltrate was present in biopsied specimens, but no frank vasculitis was detected. Of particular interest, at the time of the second presentation to the hospital, the patient's marked eosinophilia had resolved despite her progressive clinical deterioration. This may indicate that the link between eosinophilia and clinical symptomatology is not absolute.

Glucocorticoids have reportedly been beneficial in some patients with EMS. In this patient, steroid therapy may have accounted for the resolution of eosinophilia but it did not stop the progression of the disease. Plasmaphoresis and methotrexate were similarly ineffective. It is unknown what factors might contribute to a given patient being refractory to treatment. It is possible, however, that the unusually high doses of L-tryptophan ingested by this patient caused damage that was irreversible.

Elucidation of the pathogenetic mechanism of the syndrome would be of great help in developing future treatment strategies.

Acknowledgment

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50 Years Ago

From the *Journal of the Connecticut State Medical Society*

October 1940

MEDICAL PREPAREDNESS

Whether or not these United States become engaged in active combat as World War II spreads from one continent to another, the need for preparedness at last has been recognized. Medical preparedness is but one phase of the vast program but the one which concerns each physician today. Congress has already passed and the President has signed a bill calling for military training of every man without dependents and physically qualified between the ages of 21 and 35. Physicians will not be exempt from this training. As the editor of the New York State Journal of Medicine has so aptly stated, "merely to put physicians in uniform does not make military surgeons."

Each armed unit of 1,000,000 men calls for 7500 physicians. In the event of war probably a minimum of 4,000,000 men would be mobilized and for this force 30,000 physicians would be required. Today in the medical reserve corps of both Army and Navy about 15,000 physicians, or one-half the required number, are available. It will be evident to anyone who has followed the accounts of the type of warfare now being waged that the problems of military medicine and surgery today are quite different from those even of World War I. Post-graduate military training will be necessary to prepare physicians for service with the armed forces. Even our youngest practising physicians, except those already serving with the National Guard or Medical Reserve Corps, are ignorant of the problems facing them in military service. It is upon these younger men that the burden of medical military service must fall and at present the need for them is great as shown by the dearth of lieutenants and captains in the U.S. Army Medical Reserve.

The other great problem of military preparedness, that of the examining boards, concerns more the older physicians as it is most likely that from this group over 35 years of age will be selected from these boards. Connecticut and the State Medical Society occupy an enviable position in the plans for handling the medical phases of the Selective Service Law. As outlined elsewhere in this issue of the *Journal*, the organization for this purpose will be exactly as anticipated by the Preparedness Committee of the State Medical Society. This organization has been under development here for some weeks. Due to the vision and efforts of our own Executive Secretary our Society has been asked to suggest the names of physicians to serve as examiners on local Selective Service Boards and on Medical Advisory Boards. Those thus selected will be recommended for appointment by Governor Baldwin. In only a few other States does the medical society occupy such an enviable position.

Organized medicine has been loud and repeated in its request for an official body to coordinate medical and health measures. Such an objective has been attained in the Committee on Medicine and Health of the National Defense Council under the chairmanship of Doctor Irvin Abel, immediate past president of the American Medical Association. This accomplishment is most gratifying and should be a source of great satisfaction to every physician.

It is obvious that every one share in the preparedness program, physician, lawyer, mechanic, farmer. Just how the physician may be relegated to tasks for which he is not trained or afforded no opportunity for proper training for newly assigned duties, was well exemplified in our last World War. The preparedness program is developing today along more carefully planned lines and should produce results comparable in efficiency. The opportunity is ours as a Society and as individuals in collaborating in this medical preparedness program.

—Editorial from *The Connecticut State Medical Journal*, October 1940.

Pulmonary Kaposi's Disease Diagnosis by Transbronchial Biopsy

PATRICK A. BRODERICK, M.D. AND JAMES S. KRINSLEY, M.D.

ABSTRACT—While Kaposi's sarcoma (KS) classically presents with rather typical skin lesions in elderly Jewish and Italian males, visceral lesions are also well documented. More recently the occurrence of this disease in patients with the acquired immune deficiency syndrome (AIDS) is being recognized with increasing frequency. The difficulty in diagnosing pulmonary involvement in these patients is complicated by the nonspecific clinical and radiologic presentation which may mimic opportunistic infection. Tissue diagnosis is invaluable in such instances but controversy exists as to whether such diagnosis can be reliably made by transbronchial biopsy in lieu of open lung biopsy. The authors report a case in which a patient with AIDS was diagnosed as having pulmonary KS on the basis of a transbronchial biopsy. The clinical and histologic findings are described and the pertinent literature is reviewed.

CLASSICAL Kaposi's sarcoma (KS), typically presents as one or more blue to purple patches, plaques, or nodules in the skin and subcutaneous tissue of elderly Jewish or Italian men. Visceral involvement develops during the course of the disease in up to 20% of cases.[1] A more disseminated form of the disease occurs in equatorial Africa, primarily in young men. KS has also been reported in patients treated with steroids for a variety of other diseases.[2]

More recently, KS has been recognized as a manifestation of the acquired immune deficiency syndrome (AIDS).[3] KS is most commonly seen in homosexual men with this disorder. Clinical series indicate that up to 20% to 25% of patients with AIDS may have KS; autopsy series suggest that the incidence may be even higher.[4,5,6,7]

While cutaneous violaceous plaques remain the most common manifestation of KS in AIDS, visceral lesions involving the gastrointestinal tract, liver, spleen, heart, lymph nodes, and lung have been described.[2] The last may be difficult to distinguish from opportunistic infection as cough, dyspnea, and fever are typical presenting symptoms in both.

Diagnosis of pulmonary KS by bronchoscopy has been limited by inadequate tissue samples and the difficulty of distinguishing lesions of KS from biopsy artifact, hemorrhage, and fibrosis. Unless the characteristic violaceous plaques are visualized in the endobronchial tree, the diagnostic yield of bronchoscopy has been reported to be less than 10%.[6] This is in sharp contrast to the 30% to 90% incidence of pulmonary KS in autopsy series of AIDS patients.

We report a case of pulmonary KS in a patient with AIDS who had unequivocal histologic evidence of the disease diagnosed from a transbronchial biopsy.

Clinical History

The patient, a 33-year-old black male homosexual, was diagnosed as a carrier of the human immunodeficiency virus (HIV) in 1987. In December 1988 he underwent mediastinoscopy for evaluation of asymptomatic mediastinal adenopathy. *Mycobacterium tuberculosis* was identified and he received appropriate treatment. In January 1989 his chest film showed bilateral interstitial infiltrates and he was short of breath; *Pneumocystis carinii* pneumonitis (PCP) was diagnosed by fiberoptic bronchoscopy and he was treated with trimethoprim and sulfamethoxazole. He continued this medication orally following discharge from the hospital as prophylaxis against recurrent PCP infection. In June 1989 he was hospitalized with an acute febrile illness associated with a right lower lobe infiltrate observed on chest roentgenogram. He was treated with intravenous cefuroxime with apparent symptomatic improvement but there was no resolution of the chest film findings. He was seen again three months later with a 9 kg weight loss, cramping abdominal pain, and dry cough.

Physical examination revealed a thin, chronically ill,

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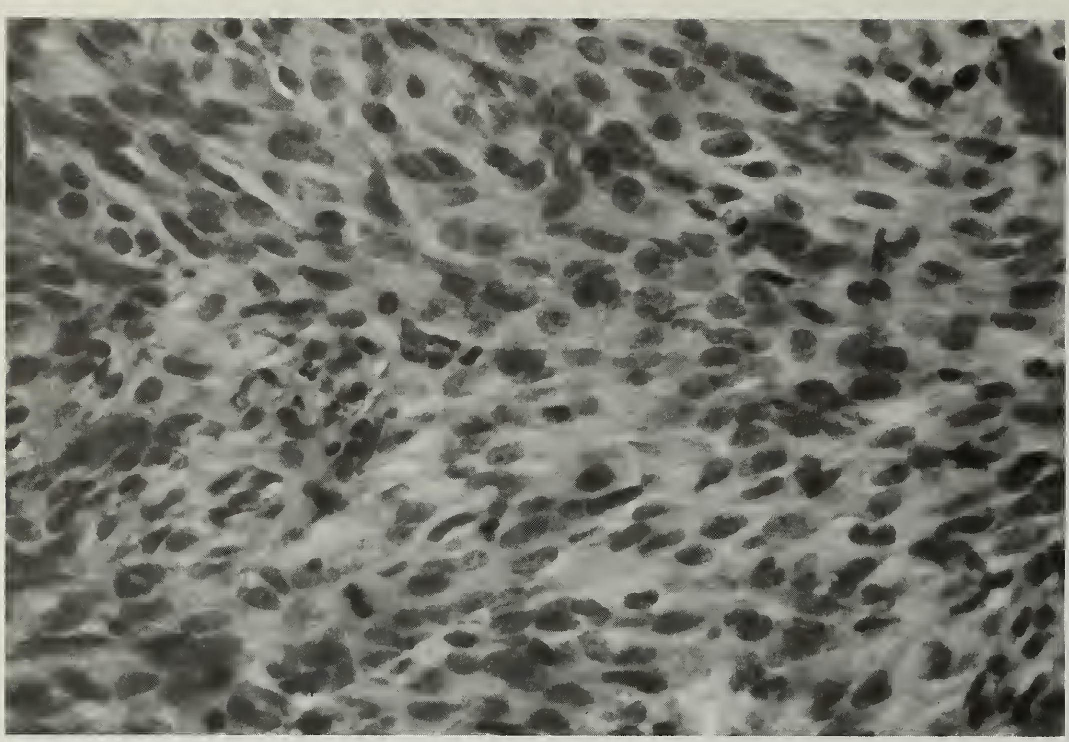

Figure 1
Predominantly spindle cell lesion including several mitotic figures
Hematoxylin and eosin stain x400

afebrile male. Findings included bilateral cervical and left axillary adenopathy, coarse right basilar crackling rales and hepatosplenomegaly. There were no skin lesions. A chest film showed progression of the right lower and mid-field infiltrates with a new left basilar infiltrate as well. The patient underwent diagnostic fiberoptic bronchoscopy with transbronchial biopsies.

Histology

The biopsies consisted of several fragments of lung tissue, in some of which there were nodular aggregates of spindle cells arranged in vaguely intersecting fascicles (fig. 1). These cells contained plump or elongated nuclei displaying moderate mitotic activity (fig. 2). Isolated cells contained intracytoplasmic hyaline bodies. The cells surrounded cleft-like spaces containing red blood cells. There were some interspersed plasma cells and lymphocytes with extravasated red blood cells.

Discussion

The role of transbronchial biopsy in the diagnosis of pulmonary KS has been controversial. Some authors deny its usefulness.[1,4,5,6,8] Indeed, a recent review states that “most clinicians and pathologists feel that pulmonary KS cannot be reliably diagnosed by transbronchial biopsy.”[9] Meduri et al[4] reviewed 11 autopsy proven cases of KS in whom endobronchial KS was visualized at bronchoscopy as cherry red, slightly raised lesions; however, the bronchial biopsy specimens were not diagnostic. In the series reported by Garay et al[10] only two of four biopsied endobronchial lesions yielded a positive diagnosis.

Nash and Fligel[11] stressed the focal nature of the neoplasm in the lung and felt that, in early cases, sufficient tissue for an acceptable diagnostic yield could only be obtained from an open-lung biopsy. Stover et al[12] were unable to diagnose pulmonary Kaposi’s disease by bronchoscopy in 11 patients despite the presence of visible endobronchial lesions strongly suggestive of Kaposi’s sarcoma in six of these patients. All of these patients were subsequently shown to have pulmonary KS based on open-lung biopsy or autopsy confirmation. Conversely, the experience of Hamm et al[13] was quite different: using fiberoptic bronchoscopy and endobronchial biopsy they were able to diagnose KS in five of six patients with AIDS.

Purdy et al[14] reviewed nine open lung biopsies and nine transbronchial biopsies from 10 patients with pulmonary KS and concluded that the diagnosis of pulmonary KS is often possible on transbronchial biopsy alone. They observed that there was a spectrum in the cytologic expression of pulmonary KS from classical KS to a pattern they described as “polymorphous KS”—the latter characterized by less spindle-cell proliferation, the appearance of nonspecific plump mesenchymal cells, more prominant lymphocytes and plasma cells, and deposition of a hyalin interstitial material between the cells. These observations may explain the difficulties encountered by pathologists in confidently diagnosing KS on transbronchial biopsies even in those cases where visible endobronchial lesions are present. When coupled with the focal nature of the neoplasm in the lungs it is perhaps understandable that false negative diagnoses occur.

Pulmonary complications of KS include airway compromise resulting from obstructing bulky tumor mass, hypoxic respiratory failure associated with progressive bilateral infiltrates, hemorrhage, which is rarely massive, and pleural effusion, which is frequently bloody. Since the presenting symptoms and radiographic findings of pulmonary KS are nonspecific, differentiation between pulmonary KS and opportunistic lung infection is usually impossible on clinical grounds alone.[5]

The preliminary work of Lee et al[15] using thallium scintigraphy as a medium in the diagnosis of KS in AIDS patients may prove helpful in limiting the differential diagnostic possibilities. However, their pulmonary experience involved only three patients and more extensive investigation is obviously indicated.

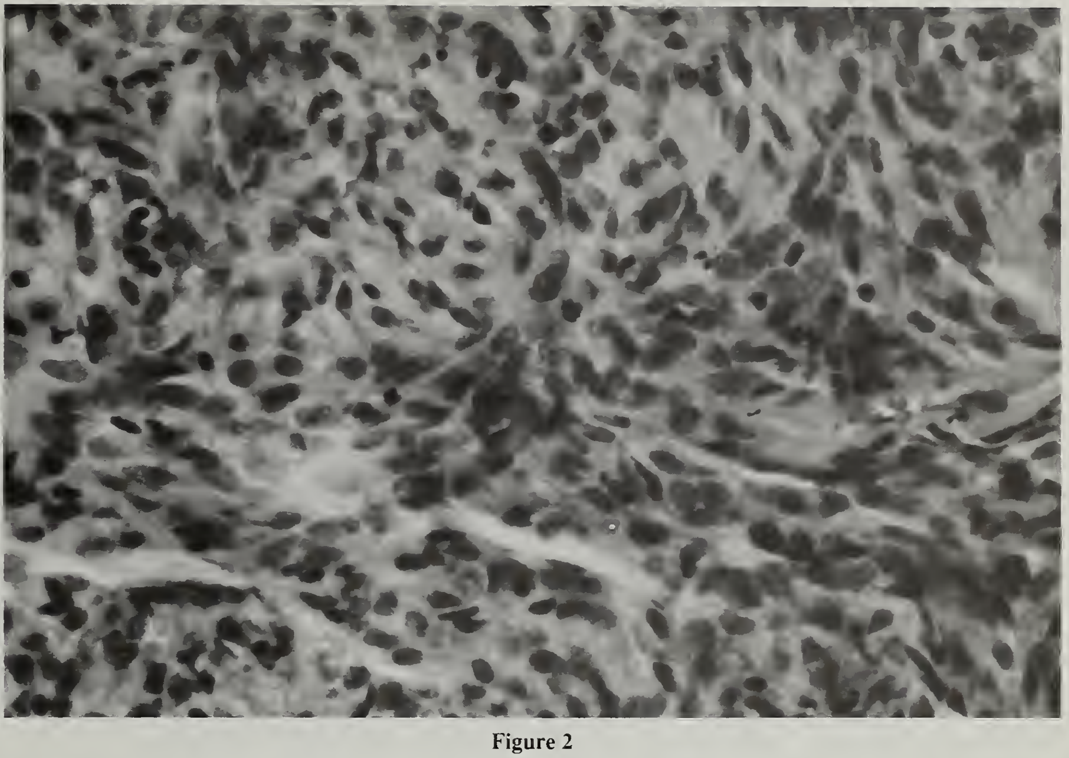

Figure 2
Tumor cells surround compressed vascular spaces
Hematoxylin and eosin stain x400

The rapidity with which pulmonary involvement occurs is noteworthy. In the six cases reported by Hamm,[13] all of whom had KS documented previously, four of five patients had been bronchoscoped, an average of 4.5 months previously (range two to nine months), with no signs of endobronchial metastases prior to the diagnosis of pulmonary KS. In the cases reported by Meduri et al,[4] the interval from initial diagnosis of KS to development of clinical symptoms due to pulmonary disease was a mean of 8.2 months (range five to 13 months). Pulmonary KS was the major cause of death in three of these patients.

Inevitably as the number of patients with AIDS multiplies, the frequency of pulmonary KS will also increase. The encouraging results of combination treatment protocols utilizing interferon alfa, AZT, and chemotherapeutic agents[16] mandates precise diagnosis. We would agree with Purdy et al[14] that transbronchial biopsies, although perhaps not always showing "classic" KS, can be diagnostic when carefully evaluated by experienced histopathologists.

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Important Advances in Clinical Medicine

Nuclear Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in nuclear medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in nuclear medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Nuclear Medicine of the California Medical Association, and the summaries were prepared under its direction.

Single-Photon-Emission Computed Tomographic Imaging of the Bone

THE planar bone scan is a sensitive test that can show altered bone physiology before it is visible by other radiographic techniques. It is not always possible, however, to determine the cause of abnormal uptake on a scintigram; therefore, specificity is low. This occurs because the images depict metabolic or blood flow alteration in bone that may be due to a variety of conditions. In addition, the planar image represents a two-dimensional summation of all the counts within a three-dimensional field of view. This results in decreased contrast between the lesion and normal tissue and in the "stacking" of bony structures on top of one another.

The application of computed tomography in nuclear medicine has been helpful in overcoming these limitations, whether imaging the skeleton or other organ systems. Instead of imaging along an anatomic plane, data are acquired every 2 to 6 degrees as the camera rotates 180 to 360 degrees around the region of interest. Computer reconstruction produces a three-dimensional image that can be sliced less than 1 cm thick along the transverse, sagittal, or coronal planes. The resulting image contains only the uptake within a particular tomographic plane of interest, thus improving contrast and anatomic localization. Single-photon-emission computed tomographic (SPECT) imaging of the myocardium has improved vessel localization in coronary artery disease, and functional brain imaging has become clinically useful now that the brain can be "sliced" to expose the region(s) of decreased perfusion.

To determine the effectiveness of SPECT over planar imaging in evaluating lower back pain, 100 consecutive patients were studied: 69 abnormalities were detected by planar imaging in 57 patients, and 90 abnormalities were detected by SPECT. None of the abnormalities noted on planar were missed by SPECT, and the lesions with low-grade uptake were better visualized by the latter technique.

Compared with plain radiography, SPECT has the added advantage of being able to determine whether an anatomic abnormality is functionally significant. Uptake within a pars interaticularis defect confirms the back pain to be due to spondylolysis or spondylolisthesis noted on plain x-ray films; the absence of uptake suggest another cause.

Single-photon-emission computed tomography enhances the interpretation of bony abnormalities of the skull, hips, and knees. It is almost as sensitive as magnetic resonance imaging in showing internal derangement of the temporomandibular joint and can be particularly useful in showing altered joint mechanics before internal derangement has occurred. Decreased uptake within an area of avascular necrosis of the femoral head

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may be "hidden" on planar imaging by the overlying acetabulum. Being able to "slice" directly through the femoral head has increased the ability to detect avascular necrosis by as much as 30%. An accurate differentiation can be made between chronic knee pain of meniscal, patellar, or degenerative origin.

Postoperatively, SPECT has been used to assess mandib-ular graft viability and to distinguish postsurgical changes from pseudarthrosis after spinal fusion. It can be used with any bone-seeking radiopharmaceutical agent, as evidenced by the uptake of neutrophils labeled with gallium 67 or indium 111 in inflammatory bone disease.

The procedure is done easily in most nuclear medicine departments in about 45 minutes with no discomfort to the patient. The relative cost is less than for other specialized imaging studies and is less than half that of magnetic resonance in the imaging of both hips for avascular necrosis.

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Single-Photon-Emission Computed Tomography of Cerebral Perfusion

SINGLE-photon-emission compute tomography (SPECT) using cerebral perfusion agent has been added to the list of noninvasive tomographic techniques currently available to evaluate the brain. It is a nuclear imaging method that creates slices of the brain similar in many ways to the images produced by x-ray computed tomography (CT) and magnetic resonance imaging (MRI). The difference is that brain images obtained with SPECT reflect regional cerebral blood flow rather than brain anatomy as is the case with CT and MRI.

Cerebral perfusion SPECT imaging is closely related to positron emission tomography (PET) in representing a physiologic rather than an anatomic imaging method. The advantages of SPECT is that it uses imaging equipment and radioactive agents that are available in most nuclear medicine laboratories, and the procedure is far less costly than PET. It is comparable in cost to CT imaging and is reimbursable by most insurers.

Cerebral perfusion SPECT imaging is done in a nuclear medicine laboratory following the intravenous injection of either of two radiopharmaceutical agents approved by the Food and Drug Administration: iofetamine hydrochloride I 123 (iodoamphetamine labeled with iodine 123) or hexamethyl-propleneamine oxime labeled with technetium Tc 99m. Both of these labeled compounds are lipophilic, which permits about 4% to 6% of the agent(s) to concentrate in the brain after passing through the blood-brain barrier. This is provided, of course, that there is sufficient regional blood flow to the territory.

Cerebral perfusion SPECT images depict regional cerebral blood flow as a map showing regional concentrations of radiopharmaceutical uptake in the brain. Uptake (regional cerebral blood flow) is highest in the cortical gray matter, basal ganglia, and cerebellar hemispheres and is normally symmetric and uniform throughout these regions. Single-photon-emission CT images of the brain that show nonuniform or reduced focal uptake suggest that these regions represent areas of decreased regional cerebral blood flow, are otherwise incapable of accumulating the radiopharmaceutical (as with nonviable or infarcted tissue), or both.

One of the principal clinical applications of cerebral perfusion SPECT imaging is in patients with stroke and related cerebrovascular disorders such as transient ischemic attacks, vascular spasm following head trauma or intracerebral bleeding (aneurysm), possible brain death, and the shunting of blood away from cortical regions due to an arteriovenous malformation.

In patients with stroke, it is common to observe areas of decreased perfusion in the ischemic regions. This often precedes the anatomic changes seen on CT or MRI. In many cases, the extent of involvement (decreased perfusion) is greater than that suggested by anatomic imaging. This may be due to the extent of ischemia associated with edema and vascular spasm, which may or may not progress to infarction.

Neurologists are showing increasing interest in using cerebral perfusion imaging to assess possible Alzheimer's disease. The procedure may be helpful in differentiating between the various causes of dementia such as Alzheimer's disease, multiple-infarct dementia, and Pick's disease. Of increasing interest among psychiatrists is the use of cerebral perfusion imaging to assess memory loss found in some cases of clinical depression (pseudodementia). In these cases, cerebral perfusion imaging shows no abnormalities.

The principal scan finding in dementia of the Alzheimer's type is a bilaterally symmetric reduction in uptake in the posterior parietal and temporal regions. Patients with multiple-infarct dementia, however, often show multiple asymmetric zones of reduced perfusion, which may or may not be associated with CT or MRI abnormalities (previous infarcts). By contrast, patients with dementia associated with Pick's disease often show decreased perfusion in the frontal lobes.

Cerebral perfusion imaging also may be done in patients with partial complex seizures to help determine the location and mesial extent (depth) of the site of seizure activity and whether it is single or multifocal. Brain SPECT imaging done immediately following a seizure has been reported to show increased perfusion (uptake) in the area of seizure activity in about 80% of patients. In the interictal period (no seizure activity), uptake may be decreased in the epileptogenic site in as many as 50% of cases.

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Single-Photon-Emission Computed Tomography of Myocardial Perfusion and the Hepatic Blood Pool

THE recent introduction of radiopharmaceutical agents that specifically depict organ blood flow has led to an explosion of interest in single-photon-emission computed tomography (SPECT). Major imaging equipment manufacturers indicate that SPECT sales are second in growth only to those of color Doppler ultrasonography.

Although the myocardial distribution of thallium 201 has been the accepted technique for the noninvasive assessment of myocardial blood flow and, hence, coronary artery disease, SPECT has considerably improved the definition of flow abnormalities in exercise, rest, and dipyridamole cardiac studies. Compared with planar imaging, SPECT can more often distinguish perfusion deficits adjacent to diaphragmatic or other extracardiac structures. The left ventricular inferior wall is much more clearly delineated. In addition, the use of the prone decubitus position for imaging has improved the specificity of the detection of inferior wall disease.

The overall sensitivity for detecting substantial coronary artery disease is above 90% with a specificity of about 75% to 80%, which surpasses that of standard treadmill tests. Stress SPECT studies following the administration of thallous chloride Tl 201 are particularly useful in women—who have an unacceptably high rate of false-positive results on standard treadmill testing—and in patients with atypical symptoms or "silent ischemia." Nevertheless, the single most important factor for a good thallium evaluation of myocardial ischemia is an adequate stress test, either using treadmill exercise or by inducing increased coronary artery flow using dipyridamole in patients physically unable to exercise because of musculoskeletal, pulmonary, or peripheral vascular disease.

Another important caveat is that certain disorders of the heart can reduce the specificity for detecting atherosclerotic coronary artery disease. Left bundle branch block may produce a relative perfusion deficit in the interventricular septum in the absence of atherosclerotic disease. Small vessel disease, cardiomyopathy, and infiltrating disease of the myocardium, such as amyloid or sarcoid, can give abnormal thallium uptake in the presence of normal large vessels on angiography.

The three-dimensional evaluation of ischemic heart disease afforded by SPECT lends itself to reproducible, semiquantitative analysis in the form of a "polar map" or "bull's eye" display of left ventricular perfusion. Individual patient data are compared with a normal data base of ^{201}Tl myocardial uptakes. Substantial areas of reduced perfusion are described in standard deviations from normal. Such quantitation can reduce interobserver variability, improve localization of specific vascular territories, and perhaps help identify diffuse and subcritical stenoses. Single-photon-emission computed tomography and quantitation can be helpful in determining which stenosis seen on coronary angiography is probably most responsible for a patient's symptoms and may be amenable to angioplasty or bypass.

New radiopharmaceutical agents (yet to be approved by the Food and Drug Administration as of this writing) labeled with technetium Tc 99m (the least expensive and most available radionuclide) promise to improve image quality and, it is hoped, reduce the cost of SPECT cardiac perfusion scans. These new agents are sestamibi (DuPont) and teboroxime (Squibb).

Technetium Tc 99m-labeled red blood cell imaging using SPECT has enabled diagnosticians to more precisely identify hemangiomas, which are the most common benign neoplasm of the liver, with a 7% incidence at autopsy. The usual scenario is that of a liver lesion detected by computed tomography (CT) or ultrasonography and referred for functional assessment. Single-photon-emission CT is superior to planar imaging for lesion detectability, particularly for smaller masses that are deeply seated in the hepatic parenchyma. Characteristically, a benign hemangioma has a decreased early flow but increased delayed blood pool within the lesion, a pattern not seen in hepatoma or metastatic lesions. Tomographic slices in the transverse, sagittal, and coronal planes can be directly compared with those of CT. Hepatic blood pool scans using SPECT are now part of the routine, noninvasive workup of liver masses of unclear significance.

The tomographic evaluation of normal and abnormal function makes SPECT a powerful tool in the hands of nuclear medicine physicians encountering these common and pertinent problems in disorders of the heart and liver.

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Gastric Emptying Revisited

RADIONUCLIDE gastric emptying studies are being increasingly used to evaluate esophageal and gastric disorders. Barium meals do not reproduce the usual patient feeding and are nonphysiologic, often cover a limited time period, and are relatively nonquantitative. In addition, radiation exposure is usually less with radionuclide gastric emptying studies despite the ability to image continuously or intermittently for hours.

Both liquid (water) and solid (chicken liver, egg, resin, and the like) meals can be used. Radiolabeled chicken liver is difficult to prepare and not palatable to some, and synthetic materials are not readily available, making a labeled egg preparation the best solid meal.

The radioactive labels used are technetium Tc 99m sulfur or albumin colloid and indium In 111 if a second label is desired to have both a radiolabeled solid component and a radiolabeled liquid component within a single meal. A liquid meal alone is usually used for children or in certain disorders and a solid meal alone in adults.

In children, ^{99m}Tc-colloid in the patient's usual feeding formula more nearly reproduces normal feeding with its usual nutrient and fat content better reflecting its effect on gastric emptying. One-minute images are taken continuously for 60 minutes. Delayed images, when needed, are obtained at 4 and 24 hours. Esophageal reflux, gastric emptying, and pulmonary aspiration are examined visually, and regions of interest are used to quantitatively evaluate gastric emptying at 60 minutes. Geometric correction is not used in adults or in children. Also, a decay correction is not made as this is considered within the normal values. The upper limits of normal for the retained gastric content of a liquid meal at 60 minutes is either 50% or less, or a half-life of 60 minutes.

Although the liquid portion of a meal may empty more rapidly than the solid portion, it is still slower than a liquid meal alone. Symptoms observed in older children and adults are usually related to the solid portion of a meal, and therefore only the solid (egg) portion of a standard meal need be labeled. If the liquid emptying is also desired, it can be done separately. Images of a minute each are taken every 10 minutes for 90 minutes. An image of a region of interest of the stomach is taken. Normal gastric retention at 90 minutes is 55% or less. This value considers the supine position during the study, the anterior-inferior descent of the meal within the stomach, the normal lag time of converting the meal to chyme, and the decay of the ^{99m}Tc. Decay corrections are never applied to the patient data but are included within the normal values.

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Hepatobiliary Excretion Scintigraphy Revisited

TO reduce the morbidity and mortality associated with acute cholecystitis, the diagnosis must be made or excluded in any patient seen because of right upper quadrant abdominal pain occurring suddenly. Ultrasonography is the procedure of choice in diagnosing the presence of gallstones, although a stone lodged in the cystic or common bile duct may often be missed. Furthermore, the presence of cholelithiasis of itself does not imply acute cholecystitis. Cholescintigraphy using technetium Tc 99m iminodiacetic acid is a sensitive and accurate examination for the presence of acute cholecystitis and biliary duct obstruction because in 98% of patients acute cholecystitis is caused by obstruction of the cystic duct.

The principal scintigraphic sign of acute cholecystitis is nonfilling of the gallbladder within an hour in spite of normal hepatic excretion, which has a false-positive rate of as high as 10% to 12% because of chronic cholecystitis, pancreatitis, nonfasting (less than 2 hours), prolonged fasting (greater than 12 hours), the use of total parenteral nutrition, alcoholism, hepatocellular disease, and severe intercurrent illness. It is claimed that the false-positive rate can be reduced by taking delayed views as much as four hours later. One study has shown that not only can the rate of false-positive results be reduced to 2% but the total study time can be reduced to an hour by administering intravenous morphine sulfate (0.04 mg per kg body weight) after 30 to 40 minutes when the gallbladder is not visualized and small bowel activity has excluded common duct obstruction. The sphincter of Oddi contracts and raises the intrabiliary pressure. Administering 2.5 mg of intravenous morphine has been shown to nearly double bile duct pressure (12.7 to 20.0 cm of saline). The maximum effect takes place about five minutes after the injection. It has been postulated that the increase in bile duct pressure may be enough to overcome partial or functional obstruction of the cystic duct and thereby raise the incidence of false-positive results. Nevertheless, it is now generally accepted that morphine-augmented cholescintigraphy is a safe and sensitive means of diagnosing acalculous and calculous cholecystitis.

Cholecystokinin and sincalide (0.02 μ g per kg) can be used to empty viscous bile from the gallbladder as seen in patients with prolonged fasting and total parenteral nutrition. The radiopharmaceutic agent is given 30 minutes after injection during the gallbladder filling phase. This procedure can also be used to contract a visualized gallbladder to test common bile duct patency. In one study common bile duct obstruction was detected in 63 of 65 patients, for a positive predictive value of 97%. The two false-positive results were caused by cholangitis of an undetermined origin. Sonographic evaluation alone, how-ever, has a high false-negative rate of 63%. It is usually wise to exclude by sonography the presence of small biliary stones that could be dislodged into the common duct.

Neonatal hepatitis can be differentiated from biliary atresia by administering phenobarbital, 2.5 mg per kg twice per day for three to seven days, to stimulate biliary secretion before administering 1 mCi (37 megabecquerels [MBq]) of ^{99m} Tc tracer. Intestinal activity seen within 24 hours in a jaundiced infant is probably due to neonatal hepatitis or prolonged hyperalimentation. A lack of intestinal activity in this time period suggest biliary atresia. The sensitivity for detecting biliary atresia is high, approaching 100% in several series. The specificity has been reported from 47% to 63% without pretreatment with phenobarbital to 63% to 94% with pretreatment.

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Captopril Renograms for Detecting Renovascular Hypertension

RENOVASCULAR hypertension occurs in about 1% of people in the general population having hypertension. Those with intermediate risk factors have prevalence rates of about 5%. Rates as high as 31% occur in persons with severe hypertension. Hence, the sensitivity and specificity of any screening test for renovascular hypertension must be greater than 90%. Until now, standard tests have not met these criteria, nor have they been shown to be practical for screening. Because the presence of renal artery stenosis does not necessarily imply the presence of renovascular hypertension, the arteriographic demonstration of renal artery stenosis in a hypertensive person is not equivalent to a diagnosis of the disorder. Furthermore, renal artery stenosis, although frequent and more severe among hypertensive patients, occurs without an associated elevation of blood pressure.

The ability to identify renovascular hypertension is important because it is amenable to surgical correction and a subsequent reduction of the blood pressure, leading to a decreased rate of hypertension-related disease and death.

Renovascular hypertension characteristically is dependent on increased renin secretion by the juxtaglomerular apparatus of an underperfused stenotic kidney. Renin acts by increasing the production of angiotension II, both a potent vasoconstrictor and a stimulator of aldosterone secretion by the adrenal cortex, prompting an increased resorption of sodium and water in the distal convoluted tubule. Glomerular filtration is maintained in the affected kidney by the vasoconstrictive action of angiotensin on the efferent arteriole. Captopril, an angiotensin-converting enzyme inhibitor, counteracts this vasoconstrictive effect, causing release of the constricting action on the efferent arteriole and a reduction in glomerular filtration. Because this effect can only be shown in patients with renovascular hypertension and not in those with essential hypertension, captopril is being used in radioisotope renography to document this effect and thus the presence of the renovascular disorder. The radioisotope renogram, as diagnostic tool for renovascular hypertension, has in the past had a sensitivity and specificity of 80% to 85%, which are not significantly better than those of the rapid-sequence intravenous pyelogram, largely because of renal diseases such as chronic pyelonephritis, obstruction, or parenchymal disease that mimic the findings. Captopril renography has become most useful in distinguishing those abnormalities that are caused by the renin-angiotensin-aldosterone effects of the disorder from those that are not.

Standard renal function evaluation techniques that use either technetium Tc 99m pentetic acid (DTPA) (excreted by glomerular filtration) or iodohippurate sodium I 131 or I 123 (excreted primarily by tubular secretion) show a delayed transit time through the kidney and therefore a prolonged excretory phase that results from the renin effect of reducing urine flow on the affected side. When captopril is administered before these tests, there is a substantial drop in the glomerular filtration rate. This affects the ^{99m}Tc-DTPA renogram by dropping the rate of tracer accumulation and the iodohippurate renogram by delaying the transit time (time to peak) and excretion rate half-time owing to the altered dynamics. These changes are not noted in essential hypertension where there is either an increase or no significant change in the glomerular filtration rate. In patients with renovascular hypertension with severely reduced renal function, the magnitude of the change may be reduced, making the test less sensitive. In those with complete renal artery stenosis, although renin production is increased, there is no handling of these radiopharmaceuticals as is to be expected. In nearly complete stenosis, there is also no demonstrable captopril effect, but an iodohippurate study does show the classic retention pattern. In mild stenosis (<50%) there is neither increased renin production nor a captopril effect.

Although large-scale studies using captopril in this manner have not yet been done, the well-defined mechanistic response to angiotensin inhibition should significantly enhance the 80% to 85% sensitivity of standard renograms in identifying renovascular hypertension and differentiating it from essential hypertension and other renal diseases.

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Dacryoscintigraphy Revisited

NASOLACRIMAL duct obstruction is a frequent cause of epiphora (excess tearing). A diagnostic evaluation is required to rule out other common causes of epiphora such as lower lid horizontal laxity or conjunctival inflammation. A proper diagnosis is essential because the traditional treatment of nasolacrimal duct obstruction is surgical correction. Recently a new technique has been described that uses a balloon catheter—like doing coronary angioplasty—to dilate the nasolacrimal duct. This has stimulated a renewed interest in a physiologic assessment of nasolacrimal duct patency.

Two office procedures may be done to evaluate nasolacrimal duct obstruction: irrigation of the lacrimal system and dye testing. Nasolacrimal duct obstruction may be diagnosed when there is complete obstruction to irrigation of the lacrimal system at the level of the nasolacrimal duct. In many patients with epiphora, however, there is no physiologic drainage of tears through the nasolacrimal duct, but forceful irrigation through the nasolacrimal duct may be accomplished (functional nasolacrimal duct obstruction). Functional nasolacrimal duct obstruction may be diagnosed by placing fluorescein dye in the eye and a cotton swab in the nose to recover the dye. This test has been criticized as unreliable because of problems recovering the dye in the nose of some patients.

The tearing process was first studied with radioisotopes in 1973. A major difference between a radionuclide dacryocystogram and an x-ray contrast dacryocystogram is that the radionuclide study is physiologic and better depicts the natural flow of tears. The study consists of placing a drop of technetium Tc 99m pertechnetate in the conjunctival space and imaging the passage of the labeled tears into the nose. X-ray dacryocystography, on the other hand, requires canalization of the nasolacrimal duct and the administration of contrast using pressure, which can mask the anomaly.

Recently 16 patients were studied before balloon dilatation of the nasolacrimal duct. In each case the dacryoscintigram showed the obstruction. In addition, the site of obstruction along the nasolacrimal path was found and the degree of obstruction was apparent. Dacryoscintigraphy is thus a useful diagnostic test to evaluate patients with epiphora and suspected functional nasolacrimal duct obstruction.

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Radiolabeled Monoclonal Antibodies for Detecting and Treating Cancer

THE use of monoclonal antibodies offers a new procedure, called immunoscintigraphy, for detecting and treating cancer. The basic concept is to use monoclonal antibodies as a carrier to transport the radionuclide to the tumor sites, using the mechanism of the binding of antibody to the site of antigen. When antibodies are labeled with √-ray-emitting radionuclides, such as technetium Tc 99m and others, they can be used to detect primary and metastatic lesions. The antibodies can also be labeled with ß-ray-emitting radionuclides such as iodine 131 and others and be applied for treatment.

Radioimmunoscintigraphy is successfully used to detect solid tumors including melanoma; hepatocellular carcinoma, neuroblastoma; carcinomas of the breast, prostate, colorectum, lung, and ovary; and nonsolid tumors such as B-cell and T-cell lymphomas. In our experience, ^{99m}Tc-anti-melanoma antibody provides excellent quality diagnostic imaging with a high tumor-to-soft-tissue ratio. Besides the known lesions that have been identified, there are many unexpected lesions detected with this radiolabeled antibody and later confirmed to be metastatic melanoma lesions. Because of the need to alter treatment plans, the clinical importance of detecting unexpected sites cannot be overemphasized. This melanoma antibody is currently under the review of the Food and Drug Administration and is expected to be approved this year. Other antibodies such as those of lymphoma, breast cancer, lung cancer, colorectal, and prostate cancer are in the early stages of investigation and available only in major medical centers.

The treatment of hepatocellular carcinoma, melanoma, neuoblastoma, B-cell and T-cell lymphomas, and ovarian carcinoma has been tried with varied but encouraging results. In one study about 50% of 105 patients with hepatocellular carcinoma responded to the treatment of ^{131}I-antiferritin antibody. Large doses (more than 200 mCi [7,400 MBq]) of ^{131}I-Lym-1 or anti-pan-B cell antibody were used to treat B-cell lymphoma with good responses in more than 30 patients.

The possible advantages of using monoclonal antibodies to detect and treat cancer are a binding of tumor-specific monoclonal antibody to the tumor site, providing high-intensity target to background images for tumor detection; a single imaging procedure and a single radiation exposure providing the information of disease in the whole body and eliminating the need for many procedures to stage the cancer; and giving a high radiation dose to tumor while sparing the normal tissue in the radioimmunotherapy.

There are several disadvantages in that only a small amount of injected labeled monoclonal antibody accumulates in the tumor. There is some nonspecific organ binding that varies with different antibodies and labeling methods. Also, all have a short shelf-life, which requires a fresh preparation.

Immunoscintigraphy and radioimmunotherapy may become an essential part of cancer staging and therapy for tumors such as melanoma, lymphoma, and carcinomas of the lung, breast, colon, and prostate.

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Treatment of Bone Metastases

SKELETAL metastases are associated with a variety of cancers, being present in more than half of patients having breast or prostate cancer. These metastatic lesions can be extremely painful despite conventional forms of therapy such as chemotherapy, surgical excision, hormonal manipulation, or localized radiation therapy. The use of radionuclides in the treatment of bone metastases has been limited to that of phosphorus 32. Its use has not been widespread, however, owing to substantial hematologic side effects in patients receiving ^{32}P therapy.

Recently, patients with widespread skeletal metastases have been treated with strontium 89, rhenium 186, and samarium 153. These radionuclides are all ß-ray emitters, with ^{186}Re and ^{153}Sm having the additional advantage of √-ray emissions that also allow for imaging.

Because the largest clinical experience in Europe and the United States has been with the use of ^{89}Sr in the treatment of bone metastases, this radionuclide will be discussed in detail.

Strontium 89 is a pure ß-ray emitter with the maximum energy of 1.5 MeV and an effective range in tissue of 0.8 cm.

It has a half-life of 50.5 days and is produced by cyclotron. It is available as an aqueous solution of strontium Sr 89 chloride for intravenous injection. Strontium 89 was reported to be effective in relieving bone pain due to metastatic prostate cancer in 80% of patients and 89% of the patients having skeletal metastases due to breast cancer. This was achieved using a dose of 40 µCi (1.5 MBq) per kilogram given as a single intravenous injection. Pain relief lasted as long six months after treatment, and retreatment at three-month intervals was possible without notable hematologic depression.

Because of the relative sparing of bone marrow by ^{89}Sr-chloride, which is a calcium analogue and not taken up directly by the bone marrow, about 20% of patients in one study showed no significant change in their leukocyte or total platelet count. The remaining 80% of the patients had an average 15% to 20% decrease in total platelets and leukocyte counts by the fifth week after ^{89}Sr-chloride was administered. A reduction in bone pain did not usually occur until 10 to 14 days after therapy, although a small percentage of patients did experience a flare phenomenon, with a significant increase in pain within 36 to 48 hours after ^{89}Sr therapy. Repeating the treatment is possible and well tolerated.

Although compounds containing ^{89}Sr, ^{186}Re, and ^{153}Sm are currently available only under investigational new drug protocols, they may be approved by the Food and Drug Administration for routine use in the near future. The use of all of the above radiopharmaceutical agents appears to have significant advantages over that of ^{32}P in the treatment of skeletal metastases, although a cure of the metastatic skeletal involvement is not possible with current dosage. Considerable palliation of pain and a better quality of life are attainable by using these therapeutic agents.

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Radionuclide Synovectomy for Chronic Joint Effusion

THE use of intra-articularly administered radiocolloid to selectively eradicate inflamed synovium was pioneered in Europe. Rather than actually surgically removing the synovium, the eventual desired outcome with this treatment is sclerosis of the synovium. Although encouraging results were initially reported in the 1960s using gold Au 198 colloid, this particular tracer had two potential drawbacks: the ^{198} Au had a √-ray emission that added to the radiation exposure with little therapeutic value, and the particle size (0.02 µm) is small, yielding unacceptable leakage from the joint. More recently, radionuclides that do not emit µ-rays and are pure ß-ray emitters have been used. The two most common are chronic phosphate P 32 and dysprosium 165 macroaggregates, which also have significantly larger particle size, thus minimizing leakage (approximately 750 µm and 5 µm, respectively).

The treatment is a simple outpatient procedure using an 18-gauge needle to do an arthrocentesis and instill the therapeutic dose, usually about 1 mCi (37 MBq) for the bone and 0.5 mCi (18.5 MBq) for an elbow. Simultaneous contrast fluoroscopy or instillation of a small dose of technetium Tc 99m sulfur colloid may be helpful to confirm the location of the needle.

Using ^{32}P-colloid or ^{165}Dy-macroaggregates for a year or more has been reported to minimize joint inflammation and effusions in 80% to 85% of patients with rheumatoid arthritis.

Chronic synovitis is a common and significant complication of hemarthrosis in patients with hemophilia. Using intra-articular ^{32}P-chromic phosphate, we have treated the knees or elbows of 25 patients with a substantial and protracted decrease in the incidence of recurrent hemarthrosis and effusion in approximately 70%.

Radiation synovectomy appears to be a viable and certainly less costly alternative to surgical synovectomy in patients disabled by chronic, large joint effusions that have proved resistant to conventional management.

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Coping with the Stress of Malpractice Litigation

CMIC Defendant Support Program

WILLIAM A. SCHEAR, M.D.

INTRODUCTION—Dr. William A. Schear, a member of the Board of Directors of the Connecticut Medical Insurance Company (CMIC) and Chairman of its Risk Management Committee, presented CMIC's Defendant Support Program to the Annual Meeting of the Physician Insurers Association of America (PIAA) in May 1990. PIAA is a national association of 43 physician owned and operated professional liability insurance companies. PIAA member companies are the source of malpractice insurance for more than half of the practicing physicians in the U.S. Among the benefits of PIAA membership for CMIC are: access to a claims data sharing project, a national lobbying effort to support important legislation, and continuing education opportunities for staff and directors.

While the need for defendant support is widely recognized, there are few formalized programs available across the nation that provide personal support services to physicians. Several PIAA companies offer published material outlining the legal process, and defendant support is available from some state medical societies, auxiliary chapters, or medical specialty groups. CMIC's defendant support program is unique in that it provides information about the legal system as well as addressing the psychological needs of physicians throughout the legal process. The following is the text of Dr. Schear's presentation.

THANK YOU for this opportunity to address an issue which is very dear to my heart - the stress of malpractice litigation. I will explain to you how our company implemented a program to support our physician defendants. First, let us consider this statement which describes the basic reasons for a physician's litigation stress:

> *Suddenly physicians and their spouses find their lives controlled by others in an atmosphere that is alien to them and which leads to a resultant sense of powerlessness and a loss of control.*

We include "spouses" because we have learned that when a physician is able to share these feelings with his or her spouse, the result is a lessening of each other's sense of isolation and vulnerability.

Historical Perspective

Let us go back for a moment to the 1300s where we find the earliest reference to the word—*MALAPRAXIS*. In those days if a physician erred and the patient died—they would cut off the first two fingers of his left hand. If the patient survived the injury but was gravely disabled, they cut off the first two fingers of his right hand. Doesn't this differentiation of punishment have a present day parallel? If the patient survives an injury, the settlement of that case could cost millions, but if he dies, the company often saves money.

Back now to the 1980s and 1990s when the punishment is mainly directed toward our wallets. Physicians could withstand this punishment by paying the ever-increasing premium, if it were not for an even greater problem—*malapraxis* cuts into our minds and our lives, too.

Physician Stress Defined

Physician-owned insurance companies, because we are run by physicians for physicians, are more keenly aware and sensitive to the enormous emotional impact of malpractice allegations against our insured members:

- We all know of at least one physician whose malpractice experience precipitated a substance abuse problem.
- We all know of at least one physician whose personal life was negatively effected by a malpractice experience.
- We all know of at least one physician whose physical health was seriously affected by a malpractice experience.
- We all know of at least one physician whose medical practice was significantly altered by a malpractice experience.

WILLIAM A. SCHEAR, M.D., Vice President, Quality Assurance/Risk Management, St. Francis Hospital and Medical Center, Hartford; Clinical Instructor, Obstetrics and Gynecology, University of Connecticut School of Medicine, Farmington.

- We all know of at least one physician whose malpractice experience deeply influenced subsequent physician-patient relationships creating a permanent suspicion of each patient's potential litigious intent.
- We all know of at least one physician whose suicide was precipitated by a malpractice experience.

This subject of physicians' litigation stress is becoming everybody's business today. Two recent books, one of which was on the best seller list, have brought these matters to the attention of the public:

Harmful Intent by Robin Cook and

Jury of My Peers by Howard Snider, Jr.

If you're interested in this subject, I'd highly recommend them to you.

CMIC's Approach

We began in 1986 to explore the feasibility of developing a defendant support program to address the emotional effect of malpractice on our insured physicians. In our preliminary discussions with defense attorneys the problems of discoverability and admissibility were identified. We polled 14 defense attorney firms, and the attorneys responded as follows:

- All agreed that the litigation process was highly stressful for all physician defendants.
- Many felt that their ability to defend a case was hampered by the inability of their clients to adjust to the fact that they had been accused of malpractice.
- Most, however, felt that the defendant support was too risky due to high probably of discoverability and admissibility of the counseling process.
- Several suggested the "lecture" format with faculty consisting of physicians who had been through the process of litigation.

Despite the legal advice of over a dozen defense attorneys, we realized that we had to persevere and address this major issue in some way. The significance of the emotional devastation to our insured members could not be denied or underestimated.

Support Group Initiated

In 1987 we began to develop a defendant support group program which would be offered to all of our insured physicians who had malpractice suits brought against them. In 1988 we invited the 110 physicians who had been sued for malpractice since the inception of our company in 1984 to attend the first session with their spouses or significant others. Thirteen physicians and three spouses attended.

Six months later, we reinvited the 97 who did not attend the first session, plus those physicians who had suits established during the six month interval. Fifteen physicians and nine spouses or significant others attended. We learned a great deal from these first two sessions:

- We had opened a Pandora's box—filled with very deep emotional problems.
- Some of the physicians and spouses were in significant need of further counseling.
- Some physicians were so upset that they needed one-to-one psychiatric assistance.
- Some physicians felt strongly about keeping their spouses out of the entire process.
- Some totally denied any emotional impact while their spouses stated otherwise.
- There was a very great need for an increased understanding of the litigation process in order for the physician to develop a winning attitude and to combat that feeling of loss of control.
- Earlier counseling at a point closer in time to the initiation of the suit would be more beneficial.

To complete the history of our program, we have held three additional defendant support group meetings: two in 1989 with a total attendance of 24 physicians and 15 spouses or significant others; and one, to date, in 1990 which was attended by 12 physicians and 8 spouses or significant others.

Support Program Status

Three years later we have a three-part support program consisting of these elements:

1. One-to-one counseling which is an individual support program. The candidates are identified in a number of ways—by claims representatives, physician colleagues, direct requests from the defendant physician, and referrals from our defense attorneys. The latter referrals are most gratifying since those very attorneys who advised against our program have bought into it and are supporting it.

   We have, to date, selected the counselors on a case by case basis, matching an appropriate counselor to a specific defendant physician. Several of our insured physicians have volunteered to act as counselors and we have taken advantage of their willingness and expertise. We found it most important for the counselor to make the initial contact with the defendant, since the latter is often reluctant to take that first step.

   The most frequent referrals come from the company's claims representatives who have learned to identify at an early point in time those physicians who are unusually upset over the initial summons.
2. The production of a resource document to serve as an education guide to the defendant physician, entitled "YOU'RE NOT ALONE". This guide is given to each physician when he or she first reports the suit to our claims representatives. It serves to provide the defendant with an informative review of the process of a lawsuit from initiation to resolution while exploring the emotional component to being sued.

3. The major portion of our program is the *Defendant Support Group* meeting held in an informal setting, usually a private club with comfortable lounge chairs and sofas. To date, we have had five sessions with five different groups of attendees. The faculty includes: a CMIC physician member of the Risk Management Committee, one of our defense attorneys, a psychiatrist skilled in group therapy, and two CMIC staff members.

The Group Meeting Format

We limit the duration of the meeting to three hours beginning with dinner. The physician moderator gives a brief explanation of why we invited the physicians and spouses to this meeting, and introduces the format and faculty. The attendees are divided into two groups:

> Group A is led by the defense attorney with the CMIC physician and one staff member available to discuss and explain the litigation process, the company's claims policies and procedures, and the vital importance of the defendant physician's participation at all stages of the defense process.
>
> Group B is led by the psychiatrist with one CMIC staff member present. This group participates in a group therapy session at which the physicians and their and their significant others are encouraged to discuss their emotional reactions to being sued. By sharing their feelings with colleagues, in the same situation, our hope is that the physicians and spouses come away with a positive attitude and better able to adjust to the situation.

We have three simple rules:

1. No minutes or notes kept.
2. No specific details of any case are discussed—and this we firmly enforce.
3. The content of all discussion must be kept absolutely confidential to those present.

Support Program Results

Now I would like to share with you our observations after conducting five defendant support group sessions. For the Company the groups have been a startling educational experience. We have become more aware of the depth of emotional devastation of our defendant physicians and their families and just how deeply affected are their practice of medicine and their personal lives. Although—especially in the group therapy sessions—CMIC realizes that we have literally opened a Pandora's box, we are so pleased that the physicians and their spouses or significant others have shown such an overwhelming positive response to our efforts. Here are some examples of the comments that the participants have made on the evaluation forms, some of which are indeed thought provoking:

"I now realize that I alienated my very supporters—my family, office staff, and colleagues—by becoming more demanding of myself and others without realizing that I had become overly critical and overbearing."

"I now feel less isolated and singled out."

"Thank you for thinking of and helping us deal with the grave impact which this matter has on practicing physicians—the depression, the loss of self confidence, the extreme mood swings, the thoughts of giving up practice—What a nightmare!"

"I had no idea that my wife and family were so affected by my reaction to the suit—she never talked about it before."

"I finally understand the litigation process and why it takes so long."

"I do not think that the wives should have been invited. A malpractice suit is a business matter not a family one."

"A single session is not enough—we should have repeat sessions with the same group as our cases progress."

"CMIC should teach us how to identify the patient who will probably sue us so we can avoid that kind of patient."

"Your session should address alternative career planning."

"Being sued for malpractice is like learning you have cancer."

Cost Savings Analysis

The cost of invitations, renting accommodations, meals, and faculty honoraria—$1,800 per session—is far outweighed by the benefits that result. Insurance Company costs are enormously increased by even one insured physician who:

- has been unable to adjust to the suit;
- refuses to supply the claims representative with details of the case;
- will not cooperate with the defense attorney—ie respond to phone calls, letters, etc.;
- refuses to attend a peer review of his case by his colleagues;
- behaves inappropriately at deposition or at trial resulting in a negative effect on the defense of the case;
- refuses to agree to a court trial when no liability exists and insists on a costly pretrial settlement or the reverse;
- refuses to settle for a small amount in a case where an anticipated negative trial judgement could well be several times that amount;
- refuses to be present at his own trial.

We believe the Defendant Support Program can minimize many of these costly claims management problems.

Conclusion

We have conducted our CMIC Defendant Support Program for over two years. We still have a long way to go. There are still many areas we have not, as yet, been able to address:

- A follow-up after the suit is settled to identify the benefits of our program.
- A better system to identify those defendant physicians who need more than our program can offer; ie continued counseling through self-perpetuating autonomous groups or sometimes private psychiatric help.
- A formal training program for our one-to-one counselors.
- A better way to involve spouses or significant others at an earlier point in time.

As a physician-owned professional liability insurance company, we have reached our goal—to have a significant effect on the professional liability market in order to offer maximum coverage to physicians at minimum premiums and to reduce the incidence of malpractice. But I think we still have another major agenda, and I would make this challenge to each of the companies in this audience:

We must help our insured physicians, who are the major providers of the health care in this country, to get through the emotional trauma of malpractice allegations so harmful to them, their families, and their defense. By doing this, we as leaders of physician-owned insurance companies will help our colleagues to preserve the physician-patient relationship, our basic daily reason for being.

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Comments on the Status of Laws Relating to Treatment of Incompetent Patients

LAUCHLIN H. MCLEAN, J.D.

Connecticut Laws

THE last session of the Connecticut General Assembly passed a new law providing for a Power of Attorney for Health Care Decisions, which, if prepared by their patients and made known to their attending physicians, should provide reassurance to those physicians treating patients who become incapacitated and who are unable to communicate with their doctors concerning decisions regarding medical treatment.

The new law supplements one in effect in Connecticut since 1985 which provides for what is popularly known as a "living will." This statute contains wording for a document which expresses the wishes of the patient, made while he or she is of sound mind, that the patient not be kept alive through life support systems if the patient's condition is deemed terminal.

This living will law applies only to conditions deemed terminal by the attending physician, and is effective only while the patient is incapacitated. A written living will is reassuring as guidance for the attending physician in such terminal cases as to the wishes of the patient, although the statute recognizes that those wishes do not necessarily have to be expressed in writing. In any event, the attending physician must obtain the informed consent of the next of kin, if known, or legal guardian, if any, of the patient prior to removal of life support systems; comfort care and pain alleviation must be provided in all cases. The Connecticut Supreme Court has said that artificial technology to assist nutrition and hydration are included within the definition of life support systems which can be removed under the living will statute. Living will forms are available now from legal blank publishing companies, from attorneys, and from the Connecticut State Medical Society.

Now the new law, Public Act 90-71, effective 1 October 1990, sets up a power of attorney for health care decisions and authorizes a health care agent appointed by a person while competent to make medical decisions for that person should he or she subsequently become incompetent. However, the new power of attorney for health care decisions law specifically prohibits the health care agent from consenting to the withdrawal of life support systems or to the withdrawal of nutrition or hydration—matters already covered in terminal cases by the living will law.

The new power of attorney for health care decisions does cover the myriad of health care decisions which do not involve withdrawal of life support systems or withdrawal of nutrition or hydration. Examples of these are: choice of physicians, whether to go to a hospital or nursing home or not, choices between alternative treatments recommended by the physician, whether to have an operation or not, etc. It obviates the necessity of getting a court approved conservator or guardian of the incapacitated patient in order to get these decisions made.

The new law was initiated in the General Assembly at the request of the Connecticut Department of Aging and was actively supported by the American Association of Retired Persons, the Connecticut Coalition On Aging, and by health care organizations. The act concerning power of attorney for health care decisions was effective on 1 October of this year. Forms for it are available.

Since the new law specifically prohibits the health care agent from consenting to the withdrawal of life support systems or to the withdrawal of nutrition or hydration, these may, and only can continue to be, covered by a living will, which applies only to a patient who is terminally ill.

Thus, it will now be necessary to execute two instruments to take full advantage of Connecticut statutes dealing with medical decisions on behalf of incompetent persons—both a living will, and a power of attorney for health care decisions.

LAUCHLIN H. MCLEAN, J.D., AARP State Legislative Committee, and retired Vice President, Aetna Life & Casualty, Hartford. Admitted to the Connecticut Bar.

Federal Constitutional Law

Since the Connecticut statutes do not authorize the withdrawal of life support systems and nutrition and hydration from an incompetent person except under terminal conditions, one must look to Federal constitutional law for guidance as to the right of a person while of sound mind to specify his wishes for removal of life support systems in nonterminal circumstances, and to have those wishes respected. Nonterminal circumstances might involve such things as a persistent vegetative state in which the patient has lost and has virtually no chance of recovering cognitive faculties but has no terminal illness (the Cruzan case decided by the U.S. Supreme Court in June 1990), and brain damage or disease which cannot be reversed and renders the patient unable to recognize people or to speak understandably but is not a terminal illness.

We have guidance from the Cruzan case. In that case eight of the nine justices on the Supreme Court indicated that there is a constitutional right for any competent individual to reject medical treatment of any kind, including life support systems, and that an expression that this rejection is to apply after an individual becomes incapacitated must be respected. A five to four majority of the court left to the states the right to define under state law the sufficiency of the expression of that rejection.

The Connecticut Supreme Court has indicated approval of clear and convincing evidence as the kind of proof required of the rejection of life support systems in nonterminal cases expressed by a person when in sound mind who later becomes incapacitated. Thus, it is best to put those desires in writing in as detailed a fashion as possible as instructions for the attending physician.

Conclusion

In Connecticut the best protection and assurances to both the patient and the physician attending an incapacitated patient can be provided by three documents (which may be combined into one): (1) a living will to cover removal of life support systems under terminal circumstances, (2) a power of attorney for health care decisions to cover all other medical decisions, except that it cannot authorize removal of life support systems under any circumstances; and, (3) under U.S. Constitutional laws, a written instrument setting forth the desires of the incapacitated patient concerning withdrawal of life support systems in nonterminal circumstances. The American Medical Association, the American Bar Association, and the AARP all provide a form for doing this in one document, and in effect recommend that this be done.

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Adjuvant Therapy for Patients with Colon and Rectal Cancer

NATIONAL INSTITUTES OF HEALTH

COLORECTAL cancer is a major public health problem in the United States. The annual incidence of colorectal cancer is more than 150,000, with approximately 110 000 new cases of colon cancer (tumors above the peritoneal reflection or more than 12 cm proximal to the anal verge) and 45 000 new cases of rectal cancer each year. Over the past 30 years, the population-adjusted incidence has remained constant at approximately 47 cases per 100 000, and thus the number of cases has increased due to population growth. These tumors are predominantly of a single histological type, adenocarcinoma. The average age at presentation is 60 to 65 years. About 75% of the individuals with these cancers will have a primary surgical resection with the hope of complete tumor eradication. Recently, mortality from colorectal cancer has decreased overall, more for rectal than for colon tumors. Despite the high resectability rate and a general improvement in therapy, nearly half of all patients with colorectal cancer still die of metastatic tumor.

Adjuvant therapy is administered in addition to surgical treatment of the primary colorectal cancer with the intent to improve outcome. Adjuvant therapy options include chemotherapy, radiation therapy, and immunotherapy that are administered before or after curative-intent surgery (ie, surgery with negative microscopic margins). Over the past three decades, many clinical studies have failed to demonstrate benefits from adjuvant therapy. Claims of efficacy have been viewed with skepticism. Recently, new data from several studies have demonstrated delays in tumor recurrence and increases in survival for specific groups of patients.

Five general principles underlie adjuvant therapy:

1. There may be occult, viable tumor cells in circulation (intravascular, intralymphatic, or intraperitoneal) and/or established, microscopic foci or tumor cells locally, at distant sites, or both.
2. Therapy is most effective when tumor burden is minimal and cell kinetics are optimal.
3. Agents with proved effectiveness against the tumor are available.
4. Cytotoxic therapy shows a dose-response relationship and therefore must be administered in maximally tolerated doses, and the duration of therapy must be sufficient to eradicate all tumor cells.
5. The risk-to-benefit ratio for therapy must be favorable for individuals who may remain asymptomatic for their natural life expectancy after tumor resection.

Numerous staging systems, including Dukes' and those of Kirklin, Astler-Coller, the Gastrointestinal Tumor Study Group (GITSG), and the Tumor/Node/Metastasis (TNM) system jointly agreed to by the International Union Against Cancer and American Joint Committee on Cancer, have been used to classify colorectal cancers. Although the modified Astler-Coller Dukes' system (MAC) is probably the most commonly used in the United States, the current TNM staging system should be utilized to accurately translate other systems into a standard format and will be used throughout this consensus statement (Tables 1 and 2).

Patients with stage II (T3-4, N0, M0, or MAC B2-3) and stage III (T1-4, N1-3, M0, or MAC $C_{1\text{-}3}$) cancers have

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NIH Consensus Development Conferences are convened to evaluate available scientific information and to resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

NIH Consensus Statements are prepared by a nonadvocacy, nonfederal panel of experts based on (1) presentations by investigators working in areas relevant to the consensus question during a 1½-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and the morning of the third day. This statement is an independent report of the panel and is not a policy statement of the NIH or the federal government.

From The Office of Medical Applications of Research, National Institutes of Health, Bethesda, MD.

Table 1
Tumor/Node/Metastasis (TNM) Staging

TX	Primary tumor cannot be assessed.
TO	No evidence of primary tumor.
Tis	Carcinoma is situ.
T1	Tumor invades submucosa.
T2	Tumor invades muscularis propria.
T3	Tumor invades through the muscularis propria into the subserosa, or into nonperitonealized pericolic or perirectal tissues.
T4	Tumor perforates the visceral peritoneum or directly invades other organs or structures.
NX	Regional lymph nodes cannot be assessed.
N0	No regional lymph node metastasis.
N1	Metastasis in 1-3 pericolic or perirectal lymph nodes.
N2	Metastasis in ≥4 pericolic or perirectal lymph nodes.
N3	Metastasis in any lymph node along the course of a named vascular trunk.
MX	Presence of distant metastasis cannot be assessed.
M0	No distant metastasis.
M1	Distant metastasis.

Table 2
Tumor/Node/Metastasis (TNM) Staging

Stage 0	Tis	N0	M0	
Stage I	T1	N0	M0	A*
	T2	N0	M0	
Stage II	T3	N0	M0	B*
	T4	N0	M0	
Stage III	Any T	N1	M0	C*
	Any T	N2, N3	M0	
Stage IV	Any T	Any N	M1	

*Dukes'.

limited disease that may be resected with curative intent but remain at high enough risk for tumor recurrence that they may benefit from additional treatment. Adjuvant therapy, as previously defined, is not applicable to patients with metastatic disease (stage IV). Individuals with stage I-disease (T1, 2 N0, or MAC A or B_1) colorectal cancer have a 5-year survival with surgery alone of at least 80% to 90%. With such a high probability of cure after surgery alone, the risk-benefit ratio for most presently available adjuvant therapy favors no further treatment for this group. Additional factors that may identify subsets within these early-stage patients most at risk for tumor recurrence are being sought, but currently TNM (or MAC) staging remains the only proved prognostic method. Thus, the approximate number of new patients in the United States each year in the conventionally defined high-risk group is 55 000 patients with colon cancer and 20 000 patients with rectal cancer. Roughly half of these individuals will die of recurrent colorectal cancer. The goal of adjuvant therapy is to reduce the expected 35 000 to 40 000 deaths per year.

Although the history of adjuvant therapy for colorectal cancer has spanned 30 years, only in the past 5 to 8 years have a number of clinical trials yielded reproducible positive results. To evaluate this recent information and resolve issues regarding adjuvant therapy for patients with colon and rectal cancer, the National Cancer Institute and The Office of Medical Applications of Research of the National Institutes of Health convened a Consensus Development Conference on April 16 through 18, 1990. After a day and a half or presentations by experts and discussion by the audience, a consensus panel drawn from specialists and generalists from the medical profession and related scientific disciplines, clinical investigators, and public representatives considered the evidence and agreed on answers to the following key questions:

1. Who is at risk for recurrence after colon and rectal cancer resection?
2. Is there effective adjuvant therapy for patients with colon cancer?
3. Is there effective adjuvant therapy for patients with rectal cancer?
4. What are the directions for future research?

1. Who Is at Risk for Recurrence After Colon and Rectal Cancer Resection?

Surgery remains the critical modality in the treatment of colon and rectal cancer. Negative surgical margins, including radial margins in the rectum and retroperitoneal margins for selected sites within the colon, must be as wide as anatomically possible. Classic oncological principles must be followed in removal of the primary tumor, the associated vascular arcade, and draining lymph nodes. No-touch techniques are not essential. The goal of any colorectal resection must be to achieve negative margins.

Clarifying the role of adjuvant therapy for colon and rectal cancer and maximizing benefit of adjuvant regimens require identifying those individuals most likely to develop recurrent disease. As a first step, patients should undergo evaluation of the remainder of the large bowel for synchronous lesions. The presence of inflammatory bowel disease, familial adenomatous polyposis, hereditary nonpolyposis colorectal cancer, or more subtle familial associations should be assessed. An abdominal computed tomographic scan for liver metastases and a preoperative carcinoembryonic antigen (CEA) level should be obtained. In patients who present with emergent perforation or obstruction, or those who undergo exploratory surgery should be done postoperatively. Pelvic computed tomography and magnetic resonance imaging are neither specific nor sensitive enough to alter the surgical approach to a rectal lesion but may add useful preoperative data. Transrectal ultrasound examination appears promising in defining depth of penetration preoperatively but needs to be studied further.

At laparotomy, complete exploratory surgery is mandatory. Colon lesions should be resected with contiguous and regional lymph nodes. Lesions adherent to contiguous organs should be resected in continuity rather than dissected free. Adequate radial margins must be obtained to minimize local recurrence in rectal lesions.

The surgical pathologist should specify the gross and microscopic extent of all surgical margins, the depth of gross and microscopic penetration, the number of nodes removed, the number involved, and whether the apical node (highest level) is positive. The disease should be defined by TNM stage. Characteristics such as venous or lymphatic invasion, perineural invasion, histological subtype, and grade should be stated.

In assessing risk of recurrence after a potentially curative resection of a colorectal adenocarcinoma, we considered the usefulness of several *possible* prognostic factors in defining subgroups of patients at low, intermediate, and high risk for recurrence. These included stage of disease, site of disease, marker status, histological features, host response parameters, and cellular and molecular characteristics.

Pathological stage is the most important determinant of risk of recurrence and survival probability after primary surgical resection of colon or rectal cancer. The degree of penetration of the primary lesion, the presence or absence of lymph node involvement, and the number of involved nodes are all significant independent risk factors. Several recent retrospective reviews and prospective trials of surgery alone for stage I and II colon cancer or stage I rectal cancer indicate that prognosis is favorable. In contrast, the prognosis for patients with more advanced stages is poor. Local recurrence after rectal cancer resection also correlates with TNM staging.

There are clear differences in natural history and patterns of failure between colon and rectal cancer that mandate testing distinct adjuvant strategies for lesions in the two sites. Therefore, separate consideration of adjuvant approaches for colon and rectal cancers is appropriate. The impact of site within the colon or within the rectum on recurrence risk and survival is less significant and will not be addressed in this consensus statement.

Elevation of a preoperative CEA level (>5 ng/mL) is an indicator of increased risk for recurrence. Elevation of CEA levels correlate with stage and histology. A normal pre-operative CEA value does not obviate the need for adjuvant therapy in node-positive patients. However, an elevated CEA level may determine a high-risk subset of patients with stage II colon cancer that is appropriate for study of adjuvant therapy compared with an observation-only control group.

Pathological features such as grade, colloid or signet ring histology, venous or lymphatic invasion, perineural invasion, and perforation have been reported to be significant in univariate analysis. However, in mulitvariate models where stage is included, many or all of these characteristics lose independent prognostic significance for recurrence or survival.

Pathological findings suggesting host response, such as mononuclear cell infiltration of the primary or reactive regional lymphadenopathy, are not reproducible prognostic features. These findings may be of greater interest in the context of current or future adjuvant vaccine trials or studies of tumor-infiltrating lymphocytes/infiltrating mononuclear cells as adjuvant therapy.

It is premature to use certain cellular or molecular characteristics as standard determinants if recurrence risk or survival in colorectal cancer. Ploidy status and S phase fraction have not consistently correlated with overall recurrence and survival. With refinement and standardization of the methodology, these biologic features may help to determine stage II subsets at high risk for recurrence.

At the molecular level, the Ki-*ras*-2 allele is frequently mutated in colon and rectal cancers, but there is thus far no clear correlation between the presence of this mutation and tumor phenotype or clinical course. Deletions of p53 on chromosome 17p and "DCC" on chromosome 18q have recently been documented and may be critical to mechanisms of tumor progression. The effects of transforming oncogenes and potential suppressor genes are highly pleiotropic. Even in the most well-defined systems of viral oncogenesis, hundreds of gene sequences change in expression, all with the potential of contributing to the final tumor phenotype. Data from several investigators suggest similar complexity of changes in gene expression and/or structure in colon and rectal cancer. Data from colorectal tumor cell lines well characterized as poorly, moderately, or well differentiated suggest that production and interaction of growth factors correlate with the degree of differentiation. The clinical significance of these findings remains to be elucidated.

Pursuit of these and future laboratory observations represents critical opportuities for companion studies to current and future trials of adjuvant therapy in colon and rectal cancer. Strategies must be implemented for obtaining optimal tissue and prioritizing assignment of available specimens to studies defining the biologic and clinical significance of these cellular and molecular characteristics in relation to etiology, mechanisms of progression, and clinical behavior of colorectal cancer.

2. Is There Effective Adjuvant Therapy for Patients with Colon Cancer?

Adjuvant therapy for colon cancer should be considered as separate from that for rectal cancer. Patterns of failure differ significantly, with local pelvic failure common in rectal cancer because of narrow radial margins defined by the anatomic limits of dissection. Colon cancer, because far fewer limits exist in the extent of surgical resection and margins obtainable, tends to fail in the peritoneal cavity, the liver, or in distant sites, with only a small component of isolated local failure. Thus, while a local modality such as radiotherapy may have an important role in the rectum, it is limited to special situations in the colon. Systemic chemotherapy or immunotherapy is the dominant adjuvant modality in colon cancer at this time.

In our identification of effective adjuvant therapies for patients with colon and rectal cancers, we have relied exclusively on data derived from prospectively randomized trials. Comparisons using historical controls are subject to bias, especially considering the changing prognosis stage for stage of these patients over time. Several aspects contribute to the usefulness of trial results in making consensus recommendations for patient care. First and foremost, an adequate number of patients must be accrued to detect treatment effects that are considered to be worthwhile but realistic. A clinical trial that fails to provide a statistically significant result might be too small to provide sufficient evidence either for or against a specific therapy. Estimates of the magnitude of treatment effects with confidence intervals to reflect the statistical uncertainty of the observed trial results are recommended. The level of statistical significance (*P* value) alone is poor measure of the magnitude of a treatment effect, as it is influenced by the sample size of the data being evaluated.

In our deliberations, we attached credibility to high-quality studies, that is, studies with a low percentage of randomized patients excluded from analysis, a large sample size, good treatment compliance, and adequate duration of follow-up. We gave relatively low credibility to retrospective subset analyses in the absence of confirmatory studies. We regarded overall survival as the primary end point for evaluating treatment effectiveness. In addition, disease-free survival was an important end point. Analyses that weigh the benefits of delaying symptoms of recurrent disease against toxic effects of adjuvant therapy are important for assessing overall treatment gains considering quality of life.

Because individual trials may not be large enough to provide convincing evidence of small but worthwhile treatment effects, meta-analyses have been performed to increase the precision for estimating such treatment effects. These evaluations of data from randomized clinical trials are also useful for putting individual trial results within the context of other available data. Although there are potential methodologic problems with such analyses that relate to the selection and variability of the studies included, these analyses can provide a global summary of treatment effects. For the recommendations made by this panel, we relied on results from individual, well-conducted trials and used the meta-analyses to provide confirmatory evidence.

In the 1960s fluorodeoxyuridine and fluorouracil were given as adjuvant agents for varying periods following surgery with a wide range of dosage schedules. Activity was demonstrable but not convincing statistically in individual trials. A recent meta-analysis suggested some benefit with the use of fluorouracil.

Levamisole alone was first tested in the adjuvant setting in a small group of nonrandomized patients with colorectal cancer described by Verhaegen. Despite the failure of this agent to produce a response either alone or with chemotherapy in metastatic disease, an improvement in survival was noted in this series.

The North Central Cancer Treatment Group and Mayo Clinic, encouraged by Verhaegen's findings, designed a clinical trial that tested the combination of fluorouracil and levamisole in the adjuvant therapy for patients with resectable colorectal cancer with stage II and stage III lesions. Quality control of data acquisition and analysis was excellent. The data are mature at a median follow-up of seven years. The combination of fluorouracil and levamisole significantly reduced recurrence. Subset analysis for stage III patients treated with fluorouracil and levamisole showed a significant improvement in overall survival. These results were considered sufficiently encouraging to recommend a confirmatory trial.

An intergroup study was designed with the same methodology but with two exceptions: patients with stage II disease were randomized to observation or to a regimen of fluorouracil plus levamisole, and those with stage III disease were randomized to the three arms of observation, levamisole alone, and fluorouracil plus levamisole; only patients with colon carcinoma were studied.

This trial was well performed. Median follow-up is three years. Levamisole alone produced no significant effect. A dramatic effect of fluorouracil and levamisole relative to surgery alone on disease-free survival and overall survival was demonstrated for stage III patients. Therapy with fluorouracil and levamisole reduced the risk of cancer recurrence by 41% and the overall death rate by 33%. Overall survival percentages at three and one half years were estimated to be 71% vs 55% for the control group. Analysis failed to demonstrate an outcome difference in stage II patients, but one to two years of additional observation is needed. Side effects from this combination were well tolerated and primarily associated with fluorouracil.

There are potential pitfalls in interpreting these results. The mechanism of action of levamisole is not understood. The positive results seen in the North Central Cancer Treatment Group/Mayo Clinic study were based on a

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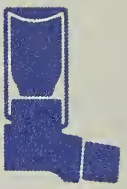

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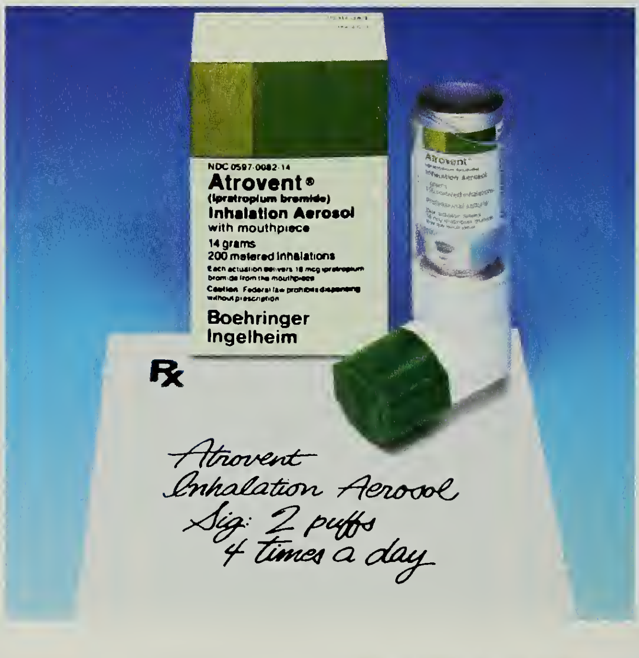

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PRECAUTIONS General Atrovent® (ipratropium bromide) should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction.

Information for Patients Patients should be advised that temporary blurring of vision may result if the aerosol is sprayed into the eyes.

Patients should be reminded that Atrovent is not intended for occasional use, but rather, in order to be maximally effective, must be used consistently as prescribed throughout the course of therapy.

Drug Interactions Atrovent has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines, steroids and cromolyn sodium, commonly used in the treatment of chronic obstructive pulmonary disease, without adverse drug reactions. There are no formal studies fully evaluating the interactive effects of Atrovent and these drugs with respect to effectiveness.

Carcinogenesis, Mutagenesis, Impairment of Fertility Two-year oral carcinogenicity studies in rats and mice have revealed no carcinogenic potential at doses up to 1250 times the maximum recommended human daily dose for Atrovent. Results of various mutagenicity studies were negative.

Fertility of male or female rats at oral doses up to approximately 10,000 times the maximum recommended human daily dose was unaffected by Atrovent administration. At doses above 18,000 times the maximum recommended human daily dose, increased resorption and decreased conception rates were observed.

Pregnancy *TERATOGENIC EFFECTS Pregnancy Category B.* Oral reproduction studies performed in mice, rats and rabbits (at doses approximately 2,000, 200,000 and 26,000 times the maximum recommended human daily dose, respectively) and inhalation reproduction studies in rats and rabbits (at doses approximately 312 and 375 times the maximum recommended human daily dose, respectively) have demonstrated no evidence of teratogenic effects as a result of Atrovent. However, no adequate or well-controlled studies have been conducted in pregnant women. Because animal reproduction studies are not always predictive of human response, Atrovent should be used during pregnancy only if clearly needed.

Nursing Mothers It is not known whether Atrovent is excreted in human milk. Although lipid-insoluble quaternary bases pass into breast milk, it is unlikely that Atrovent would reach the infant to an important extent, especially when taken by aerosol. However, because many drugs are excreted in human milk, caution should be exercised when Atrovent is administered to a nursing woman.

Pediatric Use Safety and effectiveness in children below the age of 12 have not been established.

ADVERSE REACTIONS Adverse reaction information concerning Atrovent® (ipratropium bromide) is derived from 90-day controlled clinical trials (N=254), other controlled clinical trials using recommended doses of Atrovent (N=377) and an uncontrolled study (N=1924). Additional information is derived from the foreign postmarketing experience and the published literature.

Adverse reactions occurring in greater than one percent of patients in the 90-day controlled clinical trials were as follows (ipratropium bromide N=254; metaproterenol sulfate N=249): *Cardiovascular:* palpitations—1.8% *v* 1.6%. *Central Nervous System:* nervousness—3.1% *v* 6.8%; dizziness—2.4% *v* 2.8%; headache—2.4% *v* 2.0%. *Dermatological:* rash—1.2% *v* 0.4%. *Gastrointestinal:* nausea—2.8% *v* 1.2%; gastrointestinal distress—2.4% *v* 2.8%; vomiting—0% *v* 1.2%. *Musculoskeletal:* tremor—0% *v* 2.4%. *Ophthalmological:* blurred vision—1.2% *v* 0.8%. *Oro-Otolaryngeal:* dry mouth—2.4% *v* 0.8%; irritation from aerosol—1.6% *v* 1.6%. *Respiratory:* cough—5.9% *v* 1.2%; exacerbation of symptoms—2.4% *v* 3.6%.

Additional adverse reactions reported in less than one percent of the patients considered possibly due to Atrovent® (ipratropium bromide) include urinary difficulty, fatigue, insomnia and hoarseness.

The large uncontrolled, open-label study included seriously ill patients. About 7% of patients treated discontinued the program because of adverse events.

Of the 2301 patients treated in the large uncontrolled study and in clinical trials other than the 90-day studies, the most common adverse reactions reported were: dryness of the oropharynx, about 5 in 100; cough, exacerbation of symptoms and irritation from aerosol, each about 3 in 100; headache, about 2 in 100; nausea, dizziness, blurred vision/difficulty in accommodation, and drying of secretions, each about 1 in 100. Less frequently reported adverse reactions that were possibly due to Atrovent include tachycardia, paresthesias, drowsiness, coordination difficulty, itching, hives, flushing, alopecia, constipation, tremor, mucosal ulcers.

Cases of precipitation or worsening of narrow-angle glaucoma, acute eye pain and hypotension have been reported.

A case of giant urticaria with positive rechallenge has been reported from the foreign marketing experience (see CONTRAINDICATIONS).

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References: 1. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc. **2.** Braun SR, McKenzie WN, Copeland C et al. A comparison of the effect of ipratropium and albuterol in the treatment of chronic obstructive airway disease. *Arch Intern Med* 1989; 149:544-547. **3.** ATROVENT full prescribing information. **4.** Tashkin DP, Ashutosh K, Bleecker ER, et al. Comparison of the anticholinergic bronchodilator ipratropium bromide with metaproterenol in chronic obstructive pulmonary disease: A 90-day multicenter study. *Am J Med* 1986;81 (5A):81-90.

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relatively small number of patients and a subset analysis. The short follow-up is a concern for the interpretation of results from the intergroup study. At this time, however, these studies are the most compelling investigations that demonstrate a statistically significant improvement in disease-free survival and overall survival in the adjuvant setting for stage III patients. Longer follow-up will hopefully strengthen the conclusion that adjuvant fluorouracil and levamisole for stage III patients should be the control arm for ongoing clinical trials and should be offered to similarly staged patients outside of trials unless medical or psychosocial contraindications exist.

If subsequent analysis of fluorouracil and levamisole demonstrates significant benefit for stage II patients, identical recommendations for trial or nontrial patients would pertain. However, the high survival rates observed in node-negative patients without adjuvant therapy would require a close examination of risk and benefit if this subset of patients were to be treated outside of clinical trials. There have been high response rates in metastatic colon cancer with the use of fluorouracil and leucovorin. This combination, with or without levamisole, is under current clinical trial investigation.

The National Surgical Adjuvant Breast and Bowel Project protocol CO1 demonstrated a significant, although modest, improvement in disease-free survival at a median follow-up of seven years using a combination of methy-chloroethyl-cyclohexyl-nitrosourea (methyl-CCNU), vincristine, and fluorouracil. This effect seems to be diminishing with time. A major concern, demonstrated in other studies as well, is the leukemogenic effect and renal toxicity of methyl-CCNU.

The GITSG protocol 6175 failed to demonstrate any benefit for the adjuvant use of methyl-CCNU and fluorouracil, methanol-extracted residue of bacillus Calmette-Guerin vaccine, or methyl-CCNU and fluorouracil plus methanol-extracted residue of bacillus Calmette-Guerin vaccine for patients with similarly staged node-positive and node-negative colon cancer.

Recognition that the liver is the most common site of tumor recurrence has led to multiple controlled and uncontrolled studies to evaluate portal vein infusion as adjuvant therapy in high-risk patients. One study combined systemic infusion with hepatic irradiation. All of these studies sought to demonstrate an improvement in regional control of hepatic metastases. Although some have reported significant improvement in disease-free survival and overall survival (presumed to be secondary to systemic effect), none, with the exception of the original study by Taylor et al, have succeeded in reducing liver metastases. This form of regional adjuvant therapy remains investigational. In view of the improved overall survival results, other approaches for using short-duration intraoperative or immediate postoperative (perioperative) chemotherapy might be investigated.

Whenever a new therapy is found to be effective in a clinical trial, it is always difficult to determine how to advise other patient groups not precisely identical to the clinical study group. Although the available clinical trial data demonstrate benefit for patients who receive their therapy within six weeks of surgery, there is no evidence that patients who receive therapy after that period benefit significantly. Because there is no appropriate way to design a prospective trial that intentionally delays therapy beyond six weeks, this question cannot be answered by existing data or by subsequent clinical trials. The decision to begin adjuvant chemotherapy in appropriate patient groups later than six weeks after surgery must be left to individual decisions between the patient and physician.

3. Is There Effective Adjuvant Therapy for Patients With Rectal Cancer?

Oncological principles of surgical removal of the primary and draining lymph nodes apply to rectal cancer as well as to colon cancer. In general, two standard surgical approaches, abdominoperineal resection and low anterior resection, have been used in these trials. In contrast to colon cancer, there is a significant risk of symptomatic local-regional failure as the only or first site of recurrence in patients with curatively resected rectal cancer. In node-negative patients, local recurrence may be as low as 5% to 10% for stage I tumors but approaches 25% to 30% for stage II tumors. In patients with stage III tumors, local recurrence rates increase to 50% or more for more invasive tumors. The principal reason for local recurrence in resected rectal cancer appears to be related to the anatomic constraints in obtaining wide radial margins, even though the proximal and distal margins are adequate. Thus, in addition to the standard treatment outcomes of overall and disease-free survival, local-regional control should be considered in patients with rectal cancer. Clearly, this is not only an academic issue, because local recurrence is associated with significant morbidity and often not effectively palliated by local treatment (surgery and/or radiation therapy) or by systemic chemotherapy at the time of recurrence.

Patients with locally invasive rectal cancer are at high risk for systemic relapse, similar to patients with locally advanced colon cancer. The systemic risk for patients with node-negative rectal cancer also appears comparable to that for patients with similarly staged colon cancer.

By definition "effective" adjuvant therapy of surgically resected rectal cancer should address both the local and systemic relapse potential of the disease. Over the past 10 to 15 years, the use of adjuvant radiation therapy has been evaluated in several randomized studies in both the preoperative and postoperative setting. An important variable in the studies of preoperative irradiation has been the total dose, ranging from a single 5-Gy fraction within 24 hours before surgery to high-dose fractionated (35 to 50 Gy in 4 to 7 weeks) irradiation over several weeks before surgery. Overall, there appears to be a significant decrease in local recurrence rates in patients who receive moderate- to high-dose (>35 Gy) preoperative irradiation (10% to 20% vs 25% to 50% in controls), usually without any impact on survival.

More recently, randomized trials in patients with resected rectal cancer have assessed the impact of postoperative irradiation. This approach allows for accurate pathological staging and inclusion of only high-risk patients in the study. An improvement in local control is found in most studies where postoperative irradiation (40 to 50 Gy) is compared with surgery alone. However, similar to preoperative irradiation, no significant benefits in terms of disease-free or overall survival are evident.

In light of a minimal, if any, impact of adjuvant radiation therapy alone on survival, it is evident that systemic treatment is necessary to improve the prognosis of patients with surgically resected rectal cancer. Several large, well-designed, randomized trials that employ systemic therapy in at least one study arm were updated at the consensus conference. The GITSG 7175 and 7180 studies, the National Surgical Adjuvant Breast and Bowel Project R-01 study, and the North Central Cancer Treatment Group-Mayo 794751 study were reviewed in detail and form the principal basis for our recommendations.

The major evidence in favor of the use of chemotherapy for systemic disease control comes from these trials. All relevant trials demonstrate an advantage for chemotherapy using fluorouracil and methyl-CCNU with or without radiotherapy for overall survival, disease-free survival, or both. The second GITSG study (7180) compared the effects of radiation therapy with those of therapy with fluorouracil or fluorouracil and methyl-CCNU. Preliminary analysis documented no difference in recurrence rates, suggesting that methy-CCNU may be unnecessary. Unfortunately, early termination of this trial makes a definitive answer difficult. In the first GITSG trial (7175), the combination of fluorouracil and methyl-CCNU with radiotherapy continues to show significant improvement in local control and survival with 10-year follow-up compared with surgery alone and somewhat better results than with either modality on its own. In the North Central Cancer Treatment Group study, with a median follow-up of six years, the same combination is shown to be superior to radiotherapy alone (using disease-free survival as the end point; overall survival is only marginally significant). In both studies, combined-modality treatment yields local failure rates about half those of single-modality therapy. In the National Surgical Adjuvant Breast and Bowel Project study, a combination of fluorouracil, methyl-CCNU, and vincristine is significantly better than surgery alone, but local failure remains high (23%). The one trial that does not fit this pattern is a study by the European Organization for Research on Treatment of Cancer (40741), in which the addition of only fluorouracil during preoperative radiotherapy had an apparently adverse effect on survival.

Overall, these results are strongly suggestive that the best current adjuvant therapy for rectal cancer involves postoperative treatment with both chemotherapy and radiotherapy. However, the absolute necessity for radiotherapy for survival benefit is by no means convincingly demonstrated at this time, and we must await the completion of current trials for clarification of this issue. Likewise, the presence of methyl-CCNU in most of the successful chemotherapy regimens is problematic in view of its demonstrated leukemogenesis and nephrotoxicity. It should be noted that the North Central Cancer Treatment Group study that documents benefits from combined-modality therapy utilized only two doses of methyl-CCNU compared with seven doses in the National Surgical Adjuvant Breast and Bowel Project and GITSG studies. Thus, if methyl-CCNU is found to be essential, it may be possible to deliver fewer doses. We are optimistic about the likely effectiveness of combined-modality therapy, but we recognize the need to study the effectiveness of combinations that do not include methyl-CCNU, such as fluorouracil and leucovorin or related combinations in concert with radiotherapy for local control.

As with the colon carcinoma trials, the majority of the adjuvant treatments in rectal carcinoma were initiated within six weeks of surgery. It is not known whether therapy initiated after that point would be beneficial. The decision to begin adjuvant chemotherapy later than six weeks after surgery must be decided individually between the patient and physician.

The administration of adjuvant therapy must be balanced against the possible deleterious side effects that might negate any beneficial effect. Long-term radiation effects, although infrequent, can be severe, including radiation enteritis and bowel obstruction, because tumoricidal doses (45 to 55 Gy) of radiation are necessary. Clearly, careful attention to the technical details of radiation therapy, including computed tomography-assisted, contrast-enhanced treatment planning to exclude small bowel and the use of multiple radiation fields, can reduce acute and chronic radiation side effects. Additionally, surgical attention should be directed to preventing small-intestine loops from entering the pelvis, using either natural structures or synthetic mesh. Chemotherapy should be administered by oncologists skilled in the administration of these toxic agents. The use of methyl-CCNU with its toxic effects remains problematic, and research should be directed toward finding effective drug combinations that do not use this agent.

4. What Are the Directions for Future Research?

The history of adjuvant treatment for colon cancer is confusing in part because of conflicting data from small, poorly controlled trials with inadequate follow-up. This experience makes it likely that major advances will require large, prospective, randomized trials with well-balanced populations, carefully stratified by known prognostic factors of significance. There have also been few supportive biochemical or immunologic data generated from recent trials to support or reject the biologic rationale on which the trial was based. Future trials hopefully should build in laboratory studies to confirm or reject the principal underlying hypothesis.

A review of existing clinical trials served to emphasize the need to continue efforts to improve the quality of trial data and need to continue efforts to improve the quality of trial data and need to apply appropriate quality-assurance measures. For example, future trials will need to use such measures to document adherence to preestablished surgical resection margins, staging and compliance with adjuvant therapy.

Although several adjuvant fluorouracil-containing combinations now show disease-free and overall survival benefits for patients with colon cancer, a wide variety of doses, schedules, routes of administration, and duration of therapy has been used. It is impossible to conclude what dose, schedule, and duration of fluorouracil therapy are optimal. Future trials should standardize drug dosage and schedule and link dosage, dose intensity, and duration to some biologic or biochemical end point. Likewise, the potential mechanism of levamisole's effect is presently undefined. Levamisole's dosage and schedule have been selected empirically, and the extent of immunomodulation achieved or even what is desirable has not been established. Although lack of rationale for the activity of the combination should not preclude acceptance of its demonstrated benefits, efforts to build subsequent clinical trials on the provocative results of the trial of fluorouracil and levamisole are hampered by the absence of data on the immunomodulatory effect, if any, or on the mechanism of action of the combination. Future clinical trials should include sufficient laboratory investigation to address these questions of mechanism of action and biologic rationale.

The highest priority for future adjuvant clinical trials in colon cancer remains the search for optimal regimens that improve disease-free survival and overall survival. At present, the fluorouracil-levamisole regimen is the standard with which new therapies should be compared. Issues that remain at high priority are the study of other modulators of fluorouracil, which include leucovorin, phosphonacetyl-1-aspartate, and others. Crucial for the understanding of these trials will be the biochemical determination of successful modulation of fluorouracil's effect, to be done in concert with the ongoing clinical trial. Other combinations that are active in advanced disease, such as fluorouracil and interferon, have merit for study provided they are built into a prospective trial design.

Adjuvant therapy is most conclusively established for patients with stage III disease. However, other groups of patients, such as those with stage II disease, possess 5-year disease-free and overall survival outcomes of 80% or less and might therefore be legitimate candidates for inclusion in subsequent prospective clinical trials with an untreated arm. Patients with early disease, such as stage 1 patients, have an excellent 5-year survival (>80% to 90%) with surgery alone and are not likely to benefit from adjuvant chemotherapy unless the development of newer prognostic markers allows one to select poor prognostic subsets. Newer prognostic markers such as DNA content, proliferative activity, surface glycoprotein, gastrin receptor, oncogenes/tumor suppressor genes, and allelic deletions may allow the refinement of prognostic groups further than presently possible with stage alone.

Although local relapse is not a common problem in colon cancer, there are certain groups (ie, TNM T4, N1, N2) that have significant local failure rates and should be included in separate clinical trials testing radiation-containing combined-modality therapies.

Two recent clinical trials suggest a disease-free and a survival benefit from the direct portal administration of chemotherapy, although the magnitude of the effect is less than that seen in the systemic therapy trials with fluorouracil and levamisole. Furthermore, neither trial reduced the frequency of relapse in the liver. Subsequent clinical trials will require the direct comparison of effective systemic adjuvant chemotherapy with a similar regimen given by regional infusion before intraportal drug administration can be a recommended alternative to systemically administered adjuvant chemotherapy.

As with colon carcinoma, the prospective clinical trial will be the major tool for defining future effective therapy in rectal carcinoma. Future trials must define the relative merits of combination chemotherapy, including fluorouracil and levamisole and fluorouracil, methyl-CCNU, and vincristine,and also newer combinations of promise, including fluorouracil and leucovorin and other biochemical techniques for fluorouracil modulation.

Current evidence indicates that combined-modality therapy can significantly reduce the incidence of symptomatic local recurrence in the disease, and the next series of clinical trials must define the proper dose, sequence, and integration of these modalities. The impact on local recurrence, disease-free survival, and overall survival must be measured against any increased toxicity inherent in the combined-modality approach.

Adjuvant therapy for colon and rectal carcinoma potentially affects 35 000 to 40 000 patients each year. These therapies, while bringing improved disease-free survival and overall survival, do entail longer and more complex treatments, and there is presently little information to answer questions regarding either physiological or financial burdens experienced by patients undergoing adjuvant therapy either within or outside the clinical trial setting. Resources need to be allocated to incorporate these important questions into the design of future trials of colorectal adjuvant therapy. In addition, differences in disease incidence and outcome observed in various ethnic and socioeconomic groups suggest a need to perform adequate adjuvant trials to address these questions.

The cost to the patient should be considered an integral part of adjunctive therapy. Ability to pay should never be a factor in a patient's decision to receive treatment. New protocols should always consider cost to the patient. Cost is not considered only in dollars. Cost can also mean quality of life. Decisions affecting the quality of a patient's life require an understanding between the patient and his or her physician. Basic qualities for all people should be hope, comfort, and freedom from pain.

Conclusions and Recommendations

In answer to the question "Who is at risk for recurrence after colon and rectal cancer resection?" the consensus panel recommends the following:

- The TNM system, based on a complete pathological description, can effectively describe risk groups for recurrence and should be used in clinical trial research and clinical practice.
- Patients with colon and rectal cancer should be studied separately when defining adjuvant strategies.
- Patients with stage III colon cancer or stage II/III rectal cancer are at high risk for recurrence and warrant adjuvant therapy.
- Anatomic or biologic features may define subsets of patients with stage II colon cancer who are at intermediate risk of recurrence sufficient to merit testing of adjuvant treatment compared with observation-only controls. These features include the following: (1) T4 N0 M0 or (2) T3 N0 M0, plus one or more of the following: (*a*) a preoperative CEA value greater than 5 ng/mL; (*b*) aneuploid DNA content; (*c*) high S phase; (*d*) colloid, signet ring, or poorly differentiated histology; or (*e*) 17p or 18q deletion.
- Patients with stage I lesions are at low risk of recurrence and should not receive adjuvant treatment.
- Correlation of laboratory observations and clinical data must be pursued to define the biologic and clinical significance of these cellular and molecular characteristics.

In answer to the question "Is there effective adjuvant therapy for patients with colon cancer?" we conclude that

- Optimal adjuvant therapy for stage II and III colon cancer has not yet been devised. Continued clinical trials in this disease are essential to discover more active adjuvant therapies.
- Based on current data from clinical trials, stage III patients who are unable to enter a clinical trial should be offered adjuvant therapy with fluorouracil and levamisole as administered in the intergroup trial unless medical or psychosocial contraindications exist.
- The panel cannot recommend any specific adjuvant therapy at this time for stage II patients outside of clinical trials.

In answer to the question "Is there effective adjuvant therapy for patients with rectal cancer?" we conclude the following:

- No adjuvant therapy is recommended for stage I patients; in contrast to stage II colon cancer, we recommend adjuvant treatment of stage II rectal cancer.
- Combined postoperative chemotherapy and radiation therapy improves local control and survival in stage II and III patients and is recommended.
- At the present time, the most effective combined-modality regimen appears to be fluorouracil plus methyl-CCNU and high-dose pelvic irradiation (45 to 55 Gy), but long-term toxicity consideration of methyl-CCNU militate against using this regimen outside ongoing clinical trials.
- Current clinical trials of combined-modality therapy are designed to improve the prognosis of stage II and III patients. Entry of patients into these clinical trials is highly encouraged.

The following directions for future research are suggested:

- The highest priority for future adjuvant trials in rectal cancer will be to integrate radiation therapy with newer fluorouracil-modulated regimens such as fluorouracil and levamisole, fluorouracil and leucovorin, or other combinations with demonstrated activity in advanced disease.
- There is a need to identify new determinants of risk to be used to select early-stage patients who are likely to benefit from adjuvant therapy.
- There is a need to incorporate into intergroup trials the appropriate basic laboratory investigation required to define mechanisms of drug action, especially in trials involving modulators of host immune response.
- There is a need to address issues of quality of life and the cost benefit of such therapies.
- There is a need to initiate trials to address questions of differences in disease and outcome observed in various ethnic and socioeconomically disadvantaged groups.

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Marc E. Buyse, M.Sc., M.B.A.: "EORTC Studies of Rectal Cancer"

Alfred M. Cohen, M.D.: "Adjuvant Therapy for Patients With Colon or Rectum Cancer—Surgical Considerations"

Harold O. Douglass, Jr., M.D.: "Ten-Year Follow-up of First Generation of Surgical Adjuvant Rectal Cancer Studies of the Gastrointestinal Tumor Study Group"

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Charles G. Moertel, M.D.: "An Evaluation of Combined-Modality Radiation and Chemotherapy for Surgical Adjuvant Treatment of Rectal Carcinoma"

Michael J. O'Connell, M.D.: "Historical Overview of Surgical Adjuvant Chemotherapy for Colorectal Cancer"

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The IOM Report and Public Health

AMA COUNCIL ON SCIENTIFIC AFFAIRS

A recent Institute of Medicine report defined "public health" as what society must do to keep people healthy and further defined it as involving the collection of data, assessment of problems, and assurance of health protection. Public health professionals include physicians, nurses, sanitarians, biostatisticians, engineers, and administrators, and epidemiology is public health's basic science. Past successes in the United States, such as increases in longevity and decreases in infant mortality and cardiovascular death rates, demonstrate that progress is possible; however, inequalities persist, for example, in infant mortality rates and availability of medical care to lower socioeconomic groups. The major responsibilities of public health departments include leading and coordinating public health efforts, controlling epidemics, carrying out disease and injury surveillance, collecting vital statistics, ensuring good medical and dental care for the indigent, environmental control, health education, and laboratory services.

THE American Medical Association (AMA) has had substantial involvement in many issues related to public health, including water and air pollution, acid rain, use of tobacco, toxic chemicals, nuclear power, radon, the acquired immunodeficiency syndrome (AIDS), technology assessment, drug abuse, nutrition, and the prevention of injuries and disease. Tensions remain between physicians in private practice and those in public health, yet each group can contribute unique skills and backgrounds. Physicians have an ethical obligation to help improve the community. This AMA report recommends formation of liaison committees, an AMA role as catalyst between physicians' groups and those representing public health workers, and closer cooperation between physicians in private practice and those in public health.

Resolution 82, which was adopted at the 1988 Interim Meeting, encouraged AMA members to work cooperatively with public health officials, strengthen public health services, and ensure health services of good quality for all citizens. Further, the resolution requested a review of the report of the Institute of Medicine (IOM) entitled "The Future of Public Health"[1] and asked for recommendations about strengthening the practice of public health. This report reviews the IOM publication, summarizes the scope of modern public health programs, lists selected public health-related activities of the AMA, and makes recommendations about how practicing physicians can work cooperatively with those in public health to improve public health programs.

IOM Report

A committee of 22 persons prepared the 225-page IOM report[1] with the assistance of five staff members. Twelve of the committee members were physicians, who had backgrounds in various medical specialities and professional activities, including public health and the private practice of medicine. Others came from the academic, legal, government, social services, or business sectors. The group held four open meetings and interviewed hundreds of people in the health professions, local and state governments, and other callings in six widely scattered states.

The IOM report defines "public health" as what society must do to keep people healthy. This includes applying

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From the Council on Scientific Affairs, American Medical Association, Chicago, Ill.

This report was presented to the House of Delegates of the American Medical Association at the December 1989 Interim Meeting as Council on Scientific Affairs Report E. The House passed the report.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of October 1989.

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science and technology, disseminating health information, and providing medical care to persons unable to purchase it privately. Carrying out these activities are persons in voluntary agencies and in public health departments. The IOM definition is similar to an AMA definition promulgated in 1964, which stated that "public health" refers to all organized community efforts, including those sponsored by voluntary health associations, medical societies, and other health-oriented groups. The IOM report concludes that the individual states must lead public health efforts on behalf of their citizens. Health department efforts should, in general, assess problems, collect data, provide environmental and other services or "assurance," and develop health policies that are concordant with democratic and judicial processes and traditions.

The IOM report states that public health activities are diverse and involve persons in many professions: nurses, sanitarians, administrators, biostatisticians, technologists, physicians, engineers, and support staff. All are united to prevent disease and promote good health. The report provides a list of subjects that public health professionals believe constitute their major problems (Appendix 1). Epidemiology is the "glue" of public health efforts. Those in public health face a formidable variety of difficult challenges, some newer, some older—for instance, diagnosis and prevention of human immunodeficiency virus infection; injuries; pregnancies of adolescents, with mothers and infants at increased risk; treatment of hypertension; Alzheimer's disease; and education about the adverse effects of using tobacco, alcohol, and illegal drugs.

The report emphasizes that programs for providing medical care to poor persons inevitably will consume a large proportion of the resources of health departments and detract from the departments' efforts to protect the population at large. Also, it notes that the development of federal programs over the past two decades to address public health issues such as clean air and water has tended to reduce resources and weaken the authority of local departments. Some state health departments have been placed under agencies responsible for income maintenance and social services, which tends to reduce the visibility of the departments and obscure their important functions.

High-level leadership in public health requires knowledge about activities as diverse as supervising laboratories that confirm human immunodeficiency virus or hepatitis B virus infection, surveying homes to determine radon levels, indentifying voluntary agencies that can help with hypertension treatment, and negotiating with city councils or state legislatures to expand immunization programs (Appendix 2).[2] Capable physicians who are well trained in the public health sciences should be strong candidates for providing such leadership. Ideally, says the report, public health departments will have continuity of good leadership under directors appointed for longer periods rather than undergoing frequent leadership changes that inhibit effective activities. Salaries should be sufficient to attract competent staff, and financial support must be adequate; however, increased resources may be necessary if epidemics or serious problems arise.

The IOM report states that while public health officials must have the ability and expertise to control continuing health problems and react effectively to emerging ones, their interaction and relationships with boards of health, community leaders, and colleagues in private medical practice also are crucial. State health departments and federal agencies should assist local departments by undertaking key studies or supplying necessary funds. Brief statements supplementing the IOM report describe the urgent need to increase funds for the medical care of indigent persons and suggest that probably no single organizational structure is suitable for all state health departments.

Some Issues and Concerns

The IOM report merits praise for examining public health activities and accomplishments in the United States. One of its most thought-provoking conclusions is that the nation's past successes in public health indicate what might be expected in the future. In that regard, the United States has experienced marked improvements in morbidity and mortality during recent decades. Specifically, life expectancy has increased steadily and infant mortality has declined steadily, [3,4] and between 1968 and 1977 declines of 22% and 32% occurred in mortality rates from heart disease and stroke, respectively. Immunization levels in schoolchildren now approach 95% against polio, diphtheria, pertussis, tetanus, measles, and rubella,[5] and the incidence of these diseases has declined drastically. Yet difficult problems remain and warn against complacency: the mortality rate of black infants still is almost twice that of white infants, [4] and preventable epidemics and diseases still occur, as shown by current experience with measles. It is believed millions of poor persons are unable to obtain care for acute illness, let alone identify physicians who will provide continuing medical care and advice.[1] As longevity increases, so does the prevalence of chronic disease among the elderly.

Several aspects of the report evoke comment. For instance, the report lists injuries, teen pregnancies, and Alzheimer's disease as impending crises for public health. But public health agencies must not be expected to handle these burdens alone: rather, all segments of society must contribute. The report describes a public health system "in disarray" and incapable of responding to new crises, yet successes in unraveling many mysteries of toxic shock syndrome, legionnaires' disease, and human immunodeficiency virus infection indicate the system can respond to serious challenges.[5,6]

Worthwhile recommendations about the mission of public health and the roles and responsibilities of local, state, and federal public health agencies appear in the report's final section. This part emphasizes the need for a statutory base for the health department, discusses the way the size of the community bears on its need for a health department, and notes that issues such as groundwater contamination, chemical releases, wastes, mental health, and occupational hazards require increased attention. It describes the wide array of political skills needed by those in public health, makes suggestions to the university faculties who will help potential public health workers develop such skills, and encourages those in public health to maintain communication with their co-workers in private practice. Finally, it urges readers to "get involved in their own communities."

The AMA and Public Health

The AMA's constitution clearly states the importance of bettering public health as an AMA goal. The first parts of Resolution 82 are also clear in their message that AMA members should cooperate with those in public health, help strengthen the quality of public health services, and ensure health services of good quality for all. According to the AMA's Principles of Medical Ethics, physicians have the responsibility of participating in activities that improve the community.

An AMA statement in 1964 defined public health as the art and science of maintaining, protecting, and improving the health of people by organized community efforts, which include communities' arrangements to provide medical services for special populations. The statement noted that public health is concerned with prevention and control of disease, with the medically indigent, and with the placing of patients in hospitals to protect the community. It indicated that state and county medical societies should collaborate with departments of public health, keeping in mind the need for a proper balance between public health programs and the private practice of medicine. It recommended that public health departments include at least the following services: vital statistics; public health education; environmental sanitation; public health laboratories if private facilities are unavailable; prevention and control of communicable diseases; and maternal, infant, and child health services if private facilities are unavailable. It also recommended that state and county medical societies periodically evaluate the activities of health departments.

In 1963, the AMA's Board of Trustees established a Committee on Environmental Mental Health to oversee physicians' interests in the relationships of people to their surroundings, especially air, water, soil pollution, radiation, population problems, and control of infectious diseases. The resulting staff component, the Department of Environmental Health, in 1970 joined with the Department of Occupational Health to become the AMA's Department of Environmental, Public, and Occupational Health. Responsibilities pertaining to these subjects now rest with the Department of Risk Assessment in the AMA's Division of Biomedical Science and Group on Science and Technology. Selected public health-related subjects and activities of the Group are listed in Appendix 3. A 17-page compendium of AMA positions on various subjects related to environmental, public, and occupational health is available from the Department of Risk Assessment.

Public Health Activities and Private Medical Practice

While relationships between private practitioners and those in public health have not always been smooth, examples do exist of the two sectors' working together to achieve such significant goals as safe drinking water and the raising of children's immunization levels. Duffy[7] states that during the late 1860s, practicing physicians tended to be supportive of cities' efforts to combat epidemic diseases through organized public health. As the 1890s approached, however, physicians faced increasing competition from their own rapidly increasing numbers and from dispensaries, well-child clinics, and settlement houses, and some began to resist public health regulations such as requiring the reporting of tuberculosis and syphilis cases.

After 1920, a split developed between organized medicine and physicians concerned with public health, as the later began to advocate national health insurance.[7] Disagreements continued through the 1960s as the federal Medicare and Medicaid programs were enacted. During the 1970s and 1980s, factors such as inflation, price controls, and limitations on funds available for care of poorer patients exacerbated the situation. According to the IOM report,[1] tension continues to exist between private practitioners and persons in public health, and controversy remains about the appropriate scope of public health activities. These issues are worthy of exploration in their own right.

It is likely that many persons in both groups do not understand the essential significance of the other group to the community's well-being.[8-10] The physician in public health may be viewed as being unable to perform the usual techniques and procedures of physicians in clinical practice. Yet the health department official must be capable of carrying out other kinds of procedures, such as preparing a multimillion-dollar budget or investigating a food-borne epidemic. The physician in public health, who is working for the good of the community at large, may view the private practitioner as more of a businessperson than a physician.

The Council on Scientific Affairs believes the suspicions of both groups are diminishing but that they should be reduced further. Intensified discussions among leaders of the two groups would be helpful. Medical societies could appoint interested private physicians to meet periodically with health department officials to discuss problems of mutual concern. Representatives of the public and of voluntary health groups might be invited, as appropriate, to participate in the discussions.

Physicians in public health and those in clinical practice ought to consider consulting with each other. For example, the health officer might be able to provide insight about the availability, need for, and efficacy of a specific immunizing agent or about treating the contacts of a patient with an unusual communicable disease. The clinician might have valuable experience to offer with different methods of treating a specific illness. The clinician might consider studying in depth one or more of the diverse subjects of public health[11,12] or volunteering to assist the department of public health, thereby adding breadth to clinical expertise while improving the department's capabilities.

Duffy[7] has pointed out that the increased governmental role in financing many varieties of medical care has narrowed a major distinguishing feature between physicians in private practice and those in public health. He emphasizes that physicians should cooperate with each other and work with political leaders to preserve the maximum possible amount of professional freedom while also guarding health. The physician working in any field should accord colleagues at least as much respect as he or she gives to the patient or the community. Surely, in the United States, in the booming, rapidly changing, stressful 1990s, the supply of people's ill health and their needs for guidance in health matters will continue to be infinite and more than sufficient to provide roles, tasks, and rewards for all.

Recommendations

The Council on Scientific Affairs recommends that the AMA undertake the following:

1. Encourage medical societies to establish liaison committees through which physicians in private practice and officials in public health can explore issues and mutual concerns involving public health activities and private practice.
2. Seek increased dialogue, interchange, and cooperation among national organizations representing public health professionals and those representing physicians in private practice or academic medicine.
3. Actively promote and contribute to increased attention to public health issues in its programs in medical science and education.
4. Continue to support the providing of medical care to poor and indigent persons through the private sector and the financing of this care through an improved Medicaid program and mandated employer health insurance.
5. Encourage public health agencies, as the IOM report suggests, to focus on assessment of problems, assurance of healthy living conditions, policy development, and activities such as those mentioned in the "Model Standards" (Appendix 1).
6. Encourage physicians and others interested in public health programs to apply the messages and injunctions of the IOM report as these fit their own situations and communities.
7. Encourage physicians in private practice and those in public health to work cooperatively, striving to ensure better health for each person and an improved community as enjoined in the Principles of Medical Ethics.

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Appendix 1.—Model Standards for Local Public Health Services and Programs*

Administration and supporting services
Aging and dependent populations
Air quality
Alcohol and other drug abuse, addiction
Chronic disease control
Communicable disease control
  Sexually transmitted diseases
  Immunization
  Tuberculosis
Dental health
Emergency medical services
Epidemiology and surveillance
Family planning
Food protection
Genetic disease control
Health education
Home health services
Housing services
Injury control
Institutional services
Laboratory services
Maternal and child health
Mental health
Noise control
Nutrition services
Primary care
Radiological health
Sanitation in:
  Child-care facilities

  - Government and nongovernment public buildings
  - Mobile home parks
  - Recreational areas
  - Schools
- School health
- Solid-waste management
- Tobacco use and addiction
- Toxic and hazardous substances
- Vector and animal control
- Violent and abusive behavior
- Wastewater management
- Water quality

Appendix 2.—A Modern Agenda for a Public Health Department*

1. Lead and coordinate public health planning and activities; ensure continuing education of staff and updating of services; work closely with Board of Health; ensure liaison with private physicians.
2. Identify and control specific hazards, including epidemic and communicable diseases, sexually transmitted disease, and AIDS; plan immunization programs.
3. Conduct surveillance and data-gathering on public health problems and health status of population; collect and analyze vital statistics; develop injury surveillance program.
4. Detect and prevent serious health problems, including chronic diseases and congenital malformations; plan screening programs for treatable conditions.
5. Ensure good-quality clinical care of poorer populations and high-risk families; provide such care if necessary, including preventable medical and family counseling.
6. Ensure mental health care for poorer populations; focus on epidemiology and prevention of mental illness, including delinquency, drug problems, psychosis.
7. Ensure dental care for poorer populations, focusing on prevention of dental caries and periodontitis; monitor water fluoridation and purification.
8. Ensure environmental control of air, water, food, soil, and hazardous and medical wastes; help control exposures to ionizing radiation, including those due to radon and low-level radioactive wastes.
9. Develop occupational health surveillance, including that for injuries and chemical injuries; help the community develop plans for technological emergencies and disasters.
10. Provide laboratory services.
11. Carry out appropriate research projects.

* Adapted from C.A. Miller[2] and P.Q. Peterson, M.D., MPH (oral communication, 26 April 1973).

Appendix 3.—Public Health-Related Subjects and Activities Receiving Special Emphasis of AMA Group on Science and Technology

Clinical Medicine

Adolescent health conference, AMA Auxiliary and Carnegie Foundation liaison; text series; suicide study.

Diagnostic and Therapeutic Technology Assessment (DATTA)

Geriatrics counseling, liaison with national groups, suicide project

Impairment evaluation (text); regional meetings

Infant mortality project

Prescription drug abuse project (PADS)

General Public Health

AIDS, role of drug abuse, monographs, conference on testing, counseling; liaison with Centers for Disease Control and other organizations

Air pollution, outdoors and indoors

Crashes, injuries, drivers' fitness, alcohol effects

Drug effects, including those of steroids

Family violence, corporal punishment

Injuries, research proposals review

Nutrition, food safety

Poison control centers, liaison

Radiation effects, UV light and skin cancer, low-level radioactive wastes, nuclear energy

Sexually transmitted diseases and their prevention

Tobacco, disincentives to growing, using, marketing

Environmental Health

Air pollution

Chemicals and their effects on reproduction; Agent Orange, formaldehyde, asbestos, etc

Environmental Protection Agency liaison and support

Ozone, global warming, acid rain

Pesticide effects

Wastes, medical, chemical, hazardous

Water pollution

Health Education

AIDS education, including programs for schools and medical students' activities

Pharmaceuticals education for physicians (text); brief descriptions for nonphysicians

Science education for primary and secondary school teachers

School health clinics

Occupational Health

Chamber of Commerce (US) and Occupational Safety and Health Administration liaison.

Occupational health services (text)

Prevention of Disease and Preventive Medicine

Advising on preventives such as automobile restraints, helmets for motorcyclists, fluoride, smoke detectors, spray systems

Institute of Medicine guidelines and review of report

Immunization and support of immunization programs

Screening for breast cancer, cervical cancer, diabetes mellitus, hypertension, osteoporosis

US Preventive Services Task Force liaison

Tobacco habituation, treatment, preventing use; snuff, chewing tobacco effects

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* Prepared by the American Public Health Association, US Public Health Service, and professional organizations of state, county, and local public health officials. Source of data was reference 1, pp 54 and 211.

HELPFUL HINTS

Comments on Physical Examination

E. TREMAIN BRADLEY, M.D.

PHYSICAL examination has always been a standard part of medical school education; afterward each doctor adopts in practice some special variations. For instance, inspection of the oral cavity traditionally involves a tongue depressor and asking the patient to say: "Ah—h—h." Doctors, and dentists too, go beyond this now, and it can be more thorough and less unpleasant for the patient. In order to inspect the pretonsillar fossa and floor of the mouth, I ask that the tongue be raised to the roof of the mouth. I then place a tongue depressor against the edge or *side* of the tongue rather far back. The tongue is then relaxed (on request) and can be pushed medially to expose the floor on that side. And there is usually no gagging.

Palpation is also an important procedure and is facilitated by holding the end of the tongue wrapped in gauze. Now it can be moved about without slipping while the oral cavity is thoroughly explored with a finger of the other hand.

Breast. Praises be for the advancements in definition of mammography and for the increased adoption of self-examination. Still very important is breast examination by the physician. This usually begins with inspection. The patient sits erect with hands on her hips, thumbs backward to allow shoulders and mammae to hang loose. As she slowly raises her arms over or behind her head, lumps, dimples, or other deformities may appear. Palpating the breast upward and down may dislodge a lesion from an intercostal space, bringing it out over a rib where it is more easily detectible. With the patient in the supine position the same "vertical" palpation is useful. To check for discharge the areola should be gently compressed first before "milking" the nipple between thumb and forefinger.

When the axilla is palpated for nodes, it is advantageous to place the fingers first on the skin of the lateral chest wall about an inch below the apex of the axilla. Then as the highest nodes are sought, there is no stretching of the skin that is more firmly fixed to the inner aspect of the arm. So the patient suffers less discomfort, and the examiner, without the pressure of tight skin against his finger tips, maintains better sensitivity for the detection of nodes.

Abdomen. When abdominal palpation is instituted, the muscles almost automatically tighten up. To promote their relaxation, pressure by the palpating hand is slowly eased during inspiration by the patient, and then gently followed in deeper as the breath is released. A very tense abdomen can also often be relaxed by the examiner loosely rolling the patient's leg in and out several times.

Vir-gina. Examination of the virginal vagina presents a problem. First and most important is a careful explanation to the patient about the procedure. The approach should be gentle and gradual, accompanied by verbal assurances during the process. To avoid pain a gloved, lubricated *little* finger may be introduced anteriorly, getting above the hymen. A gentle downward pull on the hymen, from above (from inside), is gradually moved over to a posterolateral position. With the finger slightly further in, posterolateral pressure relaxes the levator muscles too. This is helpful preparation for the actual examination. A PAP smear should not be taken since lubricant was used.

PAP. Since the presence of lubricant distorts the cells and makes reading of Papanicolau smears difficult and unreliable, it should not be used during any examination when a PAP smear might be indicated. Also, if two smears are taken, the first should be "fixed" promptly—as by spray if only one slide is being used. Otherwise each slide is "fixed" separately and immediately to avoid distortion of the cells by drying.

E. TREMAIN BRADLEY, M.D., solo practice of General Surgery; retired to Norfolk.

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Editorial

Guest Editorial

Reductionist Biology and Population Medicine—Strange Bedfellows or a Marriage Made in Heaven?

An important contribution, in the form of a House of Delegates-approved policy report from the American Medical Association Council on Scientific Affairs, appears elsewhere in this issue of the *Journal*. Entitled "The IOM Report and Public Health,"[1] the Council report does three things very well: (1) it clearly and precisely summarizes one of the best and potentially most effective and influential Institute of Medicine reports of recent years; (2) it delineates the little-known, inadequately appreciated but extensive history of the relationships and interactions among the public health establishment, the community of practicing physicians, and the American Medical Association over the years; and (3) it presents a series of recommendations for physicians and organized medicine to follow vis-à-vis the public's health and society's efforts to optimize the health of its citizenry.

After describing the broad array of disciplines and professionals that must be brought to bear on the complex health problems and issues facing society and pointing out that the health care of the poor is among the primary responsibilities of public health, the Council emphasizes the need for physicians from the practicing community to join their public health practitioner colleagues in the major efforts aimed at preventing disease and promoting health. The shared goal of all professionals involved in the health field is to minimize suffering and disease; it is in the pursuit of this shared goal that both sets of professionals must overcome barriers, old and new, to achieve a higher level of cooperation.

The report effectively traces the history of relations between the public health establishment and that of the practicing clinical community. Trouble began to surface in the late 19th century when public health clinics were seen by some physicians as competitive; relationships soured further shortly after World War I, when public health workers tended to support national health insurance. Post-World War II federal initiatives in health care for the poor and elderly exacerbated already sensitive relations; the Institute of Medicine report states that tensions and controversy still exist between the diminution of the tensions and suspicions on the parts of both groups and recommends intensified discussions among leaders of both groups, beginning at the local medical society level. Excellent specific suggestions are made that should be read by all physicians.

Clearly, working together in the society's best interests is a crucial goal in these times; to do so requires trust and understanding sufficient to accord to the other party the freedom to think as he or she will about financial matters or political strategies. This kind of understanding is lacking, and, in my view, the primary cause of this misunderstanding, distrust, and inadequate degree of mutual respect is not hinted at in the Council's report. I have come to believe that the most fundamental issue separating the medical clinician from the public health practitioner is the differing scientific paradigms under which they operate and conceptualize their activities. These paradigmatic differences bring our attention right back to professional education and thus force inclusion of academic health center faculties in the ultimate solutions of these tensions.

In brief, most physicians and medical school faculties operate under the Newtonian, reductionist, biomedical model, which emphasizes the understanding of disease and therapeutics at the molecular level. "One gene, one enzyme, one protein, one disease" fairly describes the overarching gestalt of modern medicine, which has become associated with specialization, superspecialization, and an explosion of interventions and technologies, which in turn have given us most of the benefits of modern health care. The doctor focuses on one patient and, from moment to moment, on the precise molecular intervention that will bring about a particular effect.

The public health practitioner, on the other hand, works with a variety of disciplines, epidemiology being at the center. Such professionals think about populations, demographic trends, and overall morbidity and mortality statistics; they try not to be overly impressed by individual results and to maintain a healthy skepticism about claims not based on sound statistics; and all too often they may have had minimal intellectual exposure to biology and biomedicine. It is no wonder that the two groups feel a chasm between them, but, parenthetically, it is also clear that public health practitioners with medical training and backgrounds have an especially important role to play in bringing the two fields together.

Each field needs the other; this can be seen from the bad vibes the public gets from our unsatisfactory infant mortality figures and the rap that gets placed on our doctors and hospitals as a result, when the issue is mostly public health in nature. Alternatively, in all the comparisons of late among health care systems of the United States, the United Kingdom, and Canada, it is rare that anyone points out that America has done by far the best job in reducing smoking in its population and in taking aggressive measures to minimize exposure of the public to the smoke of others. Alternatively, it seems to me, the high-tech medicine of our most advanced hospitals not only provides an extraordinary array of interventions for individual patients, but provides hope for all the citizenry as potential patients. This population-based hope allows us all to believe that if something dreadful befalls us, we too might have a chance at dramatic interventions and a typically American new beginning.

Public health practitioners and practicing physicians are ultimately in the same boat as professionals seeking to improve the health of our patients and our citizenry. We can do that together better than apart; and we can come together better with an enlarged understanding of what we each do, of the history of our relationships, and of the nature of the understandably different scientific paradigms that tend to govern our daily professional activities.

Roger J. Bulger, M.D.

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Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similiar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

IS ETIQUETTE ELITISM?

All the education they receive will be in vain if they do not learn good manners. (Mahatma Ghandi)

In a recent commentary appearing in *Connecticut Medicine*,[1] editor Robert Massey laments the diminishing scope of knowledge of medical students. In a test of cultural literacy these students could identify less than one third of the names and concepts relating to art, classic literature, history and so forth. Perhaps to ease the dismay of the physicians who read the article, Dr. Massey tells us that law and MBA students did slightly worse!

These results should come as no surprise. In his book *Cultural Literacy*, E. D. Hirsch[2] documents and analyzes the overall decline in the classical knowledge of American students at every level. For more than a decade verbal Scholastic Aptitude Test scores have fallen. While Medical College Admission Test scores have remained stable, [3,4,] medical schools, now faced with reduced numbers of first year applicants, have begun selecting college graduates with lower grade-point averages.[5] According to some authorities, this decline in classic information in part also accounts for the lower scores of those taking the certifying exam in Internal Medicine.[3]

From this cultural illiteracy another embarrassment has also arisen. Like many of the over-50 physicians, I sense a lack of "polish" in this new crop of physicians. As Shakespeare described the situation, "True it is that we have seen better days." The decorum which formerly was emphasized during attending rounds in our training now apparently receives short shrift. Older physicians seem particularly critical of the attire and the behavior of their younger colleagues.

Today's physicians have abandoned dress codes. Acceptable professional clothing now includes dirty and frayed jogging shoes, unkept faded blue jeans and ill-fitting scrub suits. "Is this a hospital or Club Med?," quipped one irked physician. The inappropriate garb may be associated with a lack of personal grooming. Soiled hands, dirty nails, bedraggled hair, or untidy beards offend both patients and staff. Nor should we overlook the ubiquitous stethoscope wrapped around the neck like some *écharpe du honneur*, or perhaps an albatross. Is it needed to convince patients that the disheveled person is indeed a physician?

Common courtesy and civility, too, are vanishing. While there are no rigid standards of "medical manners" certain norms of conduct are expected. Rudeness can now be seen in the herd-like rushes into lecture rooms or at the tables during professional luncheons. Lack of interphysician (or nurse) communication ranks as one of the more arrogant, if not hazardous, offenses. There seems to be little regard for transgressions or interruptions, and "please" or "pardon me" are no longer heard.

Younger physicians have told me that these criticisms reflect "elitism" on the part of older doctors. Others attributed poor manners to the demeaning experience of medical training. These seem weak palliations. Possessing good manners does not stem from some higher social standing, real or imagined. Nor should bad manners result from medical training. Character is established long before entering medical school. In a provocative essay on entitlement, Steven Dubovsky[6] characterizes many of today's medical students (and doctors) as individuals expecting "success, income and other benefits without having to give anything in return." One of the five salient features of entitlement is the student's right "to feel good even if it makes other feel bad." However, criticism of the student's own behavior is considered too stressful! Dubovsky suggests that the best way to counteract the concept of entitlement in medical students is to expose them to medical educators who themselves do not believe they are entitled to a special status.

At least two recent studies[7,8] confirm patients' preference for what they consider appropriate physician etiquette and attire. The lesson to be learned from these reports appears to be that looking like a doctor is as important to patients as behaving like one. Furlow's paper "Clinical Etiquette"[9] should be required reading for all physicians. Manners, wrote Letitia Baldridge[10] are little more than being thoughtful and kind to others. They are a mark of self-confidence. Surely, these are admirable qualities in any physician and there is nothing elitist about that. Physicians who are discourteous and ill-kempt offend both colleagues and patients. "No one is out of character," my father liked to say. "Class" is instinctive—it cannot be switched on and off.

Dr. Massey concludes that "Medical educators are *starting* (emphasis mine) to pay attention to these matters. . ." I fear they are too late. In 1983 in a symposium at Stamford University on getting humanism back into medical education,[11] Dr. Saul Rosenberg noted "that students coming into medical school know a lot of facts. . . but they are deficient in other skills such as communication, judgment and humanism." He concluded, "Premeds who are nerds, become doctors who are nerds and spouses and parents who are nerds." To this I would add: And nerd doctors also become nerd professors who train more nerd doctors and so ad infinitum.

Lee Sataline, M.D.

Cheshire

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For example, on a December evening in 1820, Dr. Eli Todd described to his colleagues in Hartford a new, more humane concept for the treatment of the insane. Within two years the Connecticut State Medical Society had emptied its treasury in this cause, and although numbering only two hundred members, had organized a subscription campaign, collecting the present-day equivalent of some two million dollars to launch the Hartford Retreat, now known as the Institute of Living, and its subsequent revolution in psychiatric care.

The approach of our Society's bicentennial must be more than a celebration of antiquarian interest. It must also be the occasion for a renewal of the spirit of the profession, a quest by our finest minds for a lasting memorial worthy of our great predecessors and their perennial ideals. Are we capable of creating a heritage that our successors will celebrate a century or two hence?

CMIC, CPRO, the Medicare Courtesy Card (ConnMap), CSMS-IPA, M.D. Health Plan, and the CSMS Charitable Trust were all launched in the 1980's. If these achievements are any indication, the outlook for the 90's is bright. Even now, CSMS has embarked on a major project to help educate the public in health promotion and illness prevention. This may well be the last major practical method for increasing quality of life while reducing health care costs in the future.

The bicentennial clock is at twenty months and counting. We must enlist medical historians with long memories to update the Society's history, last compiled and published in the sesquicentennial year of 1942. We must see that the House of Medicine is still in order, still united, and fit for a third century of leadership and progress. It is well to be inspired by the glories of the past and by the promises of the future, but most important for us, the living, are the possibilities of the *present*.

For this great body of six thousand learned and motivated leaders, as for any single one of them, "within each moment there slumbers the possibility of its being the eschatological moment." We had such a moment in 1792, and in 1822, and in a good number of years since. Might we not have another in 1992?

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The Middle Class and the Old Morality

ROBERT U. MASSEY, M.D.

EXCEPT for a skit by the students reenacting Chamberlain's visit to Munich and his Prayer Book reference to peace in our time, I remember little about social studies in high school. There was talk of society's class structure, and my friends and I speculated about our place in the social order; we were clearly neither upper nor lower class, but we were not all the same either. We decided that the middle class, to which we seemed to belong, was further divided into upper-middle, middle-middle, and lower-middle depending on the make of the family sedan. We doubted if we knew anyone belonging to the other two classes except maybe one whose father owned a well-known dairy. He might have been upper class; his mother sometimes brought him to school in a big LaSalle. Doctors' kids were upper-middle; on rainy days they arrived in Buicks. Most of our families drove Chevys, Fords, or Plymouths. We were pleased to be in the middle class because we had heard that the strength of the nation depended on us, and that some South American countries were in trouble because they had no middle class.

That all seemed self-evident to me until the 1960s when word got around that the middle class was at the root of all social evils, and middle-class morality was the worst kind, really not moral at all, but only a thinly disguised scheme to rule the roost. The implication was that true morality was and always had been the property of the lower classes; middle-class virtues like honesty, prudence, frugality, sobriety, purity, and duty were hypocritical cover-up words. In truth, there were no virtues, with the exception of tolerance. This has been a recurring theme, especially appealing in a pluralistic society like ours. Ethics without virtue, learning without content.

Last week in our town the health director reported that syphilis was now the most frequently reported infectious disease, up 150% in the last two years. The numbers are small, but the state has reported a five-fold increase in the last four years in contrast to the nation's modest increase of a mere 60%. Ours is a middle- to upper-middle-class suburban community; alcohol and tobacco abuse among the young are far more serious problems than 15 cases of a treatable venereal disease.

However, the recrudescence of *la grosse vérole* will most certainly call forth an educational effort, as if Connecticut suburbanites were not as well informed about STDs as any group in the world. But what else can we do? As physicians we follow that old Puritan, Thomas Sydenham:

> If we reject all cases of affliction which the improvidence of human beings has brought upon themselves, there will be but little room left for the exercise of mutual love and charity. God alone punishes. We, as we best can, must relieve. Neither must we be too curious in respect to causes and motives, nor too vexatious in our censorship.[1]

We remind our students not to burden their patients with "middle-class moralizing," and they remind us in turn that we, unconsciously to be sure, "invoke middle-class values," and make statements that are "culturally biased." Each of us takes pains not to offend the enlightened sensitivity of the other, but I suspect we know this is an intellectual minuet. If we continue, however, to disparage the *Tao* or its equivalent in Western culture, toward which we are indeed biased, we should not be surprised when the links holding our society together disconnect one by one. Our students and colleagues will even come to take us seriously if we let pass without comment remarks such as the authors of *Moral Education* wrote: "the 'old morality' can and should be scrapped."

The old morality never entirely prevented drunkenness, wantonness, gluttony, or cheating at cards or in business, but I have a hunch it worked better than anything else. The medical historian Oswei Temkin observed that, with the rise of the bourgeoisie and its morality based "on the family and its sanctity" at the end of the 18th century, "the incidence of venereal infection among students dwindled sharply. Moreover, the words of a luetic student, apparently writing in bodily and spiritual agony, furnish a good example of the connection between the concept of virtue and syphilis: 'Virtue is its own reward.'"[2]

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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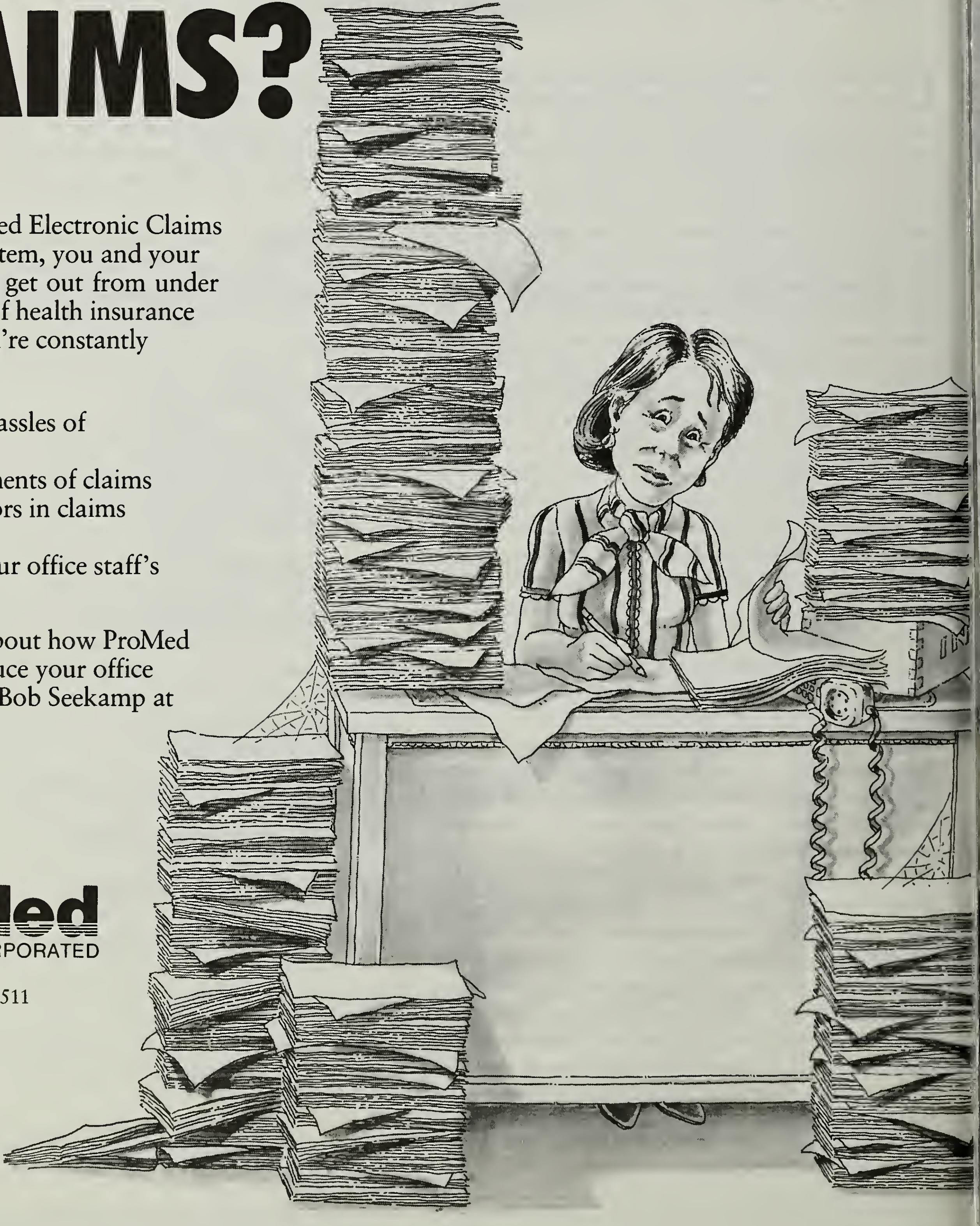

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Minors and Abortion Revisited

JOSEPH M. HEALEY

THE two cases[1] decided by the United States Supreme Court this year dealing with the constitutionality of statutes limiting minors' access to abortion suggest that in this subsection of the larger abortion controversey we are still a long way from consensus or agreement. This lack of agreement can be observed by looking at the alignment of justices in just one of the cases, the Minnesota case. Justice Stevens announced the judgment of the Court and delivered the Court's opinion with respect to parts 1,2,4, and 7, in which Justices Brennan, Marshall, Blackman, and O'Connor joined. Justice Stevens further filed an opinion with respect to part 3 in which Justice Brennan joined, with respect to part 6 in which Justice O'Connor joined, and a dissenting opinion with respect to part 8. Justice O'Connor filed a separate opinion, concurring in part and concurring in the judgment. Justice Marshall filed an opinion concurring in part, concurring in the judgment in part, and dissenting in part, in which Justices Brennan and Blackman joined. Justice Scalia filed an opinion concurring in the judgment in part and dissenting in part. Justice Kennedy filed an opinion concurring in the judgment in part and dissenting in part, in which Chief Justice Rehnquist, Justice White, and Justice Scalia joined. The result is a confusing decision in which two different 5-4 clusters of justices found some sections of the law constitutional, but others unconstitutional.

A majority of the justices acknowledged that the decision to bear or beget a child is a component of liberty protected by the Fourteenth Amendment, and that such decisions should be made independently, privately, and free of governmental intrusion. Though the right to make such decisions is an important one, it is not an absolute right, but may be outweighed by legitimate state interests. Three separate but related interests have been advanced in the context of regulating a minor's access to abortion: protecting the well-being of the pregnant minor, protecting the responsible role of parents, and preserving the family unit. With respect to the first, since immaturity, inexperience, and lack of judgement may interfere with the minor's ability to exercise rights wisely, parental involvement in the decision-making process may be justified. With respect to the second, the acceptance of the financial and custodial responsibility in parenthood may permit parents to assume a higher degree of involvement in the lives of their children than might ordinarily be accepted. With respect to the third, long-standing legal principles protect the family against undue state interference with personal decisions best made within that unit. The major issue in the *Hodgson* case would be whether any of these interests justifies restrictions on the minor's access to abortion.

Three provisions of the Minnesota statute were under review. The first required that in most circumstances a twenty-four-hour waiting period be observed. A majority of the justices concluded that this was permissible to assure that the minor's choice was knowing and intelligent. The second requirement involved notification of both parents of the minor's intent to obtain an abortion. A majority of the justices held this provision unconstitutional, concluding that requiring notification of both parents did not further any legitimate state interest. However, if this requirement were supplemented with a judicial bypass mechanism that allowed a minor to be granted permission to have an abortion, if she were sufficiently mature to decide for herself, or if the court found it was in her best interests to have the abortion, then, a majority of the Court would uphold the limitation. However, in none of the three situations under review was there unanimity among the justices, and deep division about the nature of the rights involved and the relevant data to be used in assessing the state's interests still remains.

The underlying question remains whether there will be a legislative or judicial solution to the abortion issue, given the widespread division which exists in our society, including on the Supreme Court. Ultimately, we may come to find that the most appropriate vehicle for confronting this issue and for dealing with this division may well be moral persuasion, rather than legislative or judicial coercion.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

REFERENCE

1. *Hodgson v. Minnesota*, 58 L.W. 4957 (1990): *Ohio v. Akron Center for Reproductive Health*, 58 L.W. 4979 (1990).

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From the Executive Director's Office

CALL
SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1990 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, 275 Research Parkway, Meriden. The meeting will commence at 12:30 p.m. on Wednesday, November 28, and will continue until all business has been concluded.

11:30 Registration and Luncheon
12:30 Call to Order
Mehdi S. Eslami, M.D., President
Kenneth M. Robbins, M.D., Speaker of the House
Marjorie G. Petro, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member or Postgraduate Physician Member of The Society, in compliance with the following provisions.

a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.

b. Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.

c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.

d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.

PROPOSED AMENDMENT TO THE BYLAWS

The following proposed amendment to the Bylaws was presented to the House of Delegates on May 9, 1990 and was tabled for consideration and action at the next regular meeting of the House of Delegates.

In accordance with the Bylaws, this amendment is being published in *Connecticut Medicine* "on one or more occasions prior to the next meeting—at which meeting the amendment shall be taken off the table and acted upon by the House of Delegates."

SUBJECT: DELIQUENCY

PURPOSE: TO REMOVE PENALTY FOR DELINQUENCY

The Council recommends the following changes: Article XII, DUES: Section 4. Delinquency (Deletion in brackets and capitals.) Par. 1 - An Active Member is delinquent if his dues are not paid by April 30th of the year for which dues are prescribed and shall forfeit his Active Membership in the Society if he fails to pay the delinquent dues within thirty days after notice of his delinquency has been mailed to his last known address by the Executive Director of the Society. (ACTIVE MEMBERS OF THE SOCIETY WHO HAVE BEEN DROPPED FROM THE ACTIVE MEMBERSHIP ROLL FOR NONPAYMENT OF DUES CANNOT BE REINSTATED UNTIL SUCH INDEBTEDNESS HAS BEEN DISCHARGED, BUT SUCH INDEBTEDNESS SHALL APPLY ONLY TO THE ONE FISCAL YEAR OF DELINQUENCY.)

COUNCIL MINUTES

Thursday, September 6, 1990

ATTENDANCE

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Ahamed, Beck, Blum, Bobruff, Brooks, Cottle, Deren, Eslami, Franklin, Freedman, Kamens, Keating, McDonnell, Meridy, Orphanos, Petrie, Redmond, Robbins, Sadowski, Sosa, Van Nostrand, Wetstone, Wolfson, and Zanker.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Garofalo, Ms. Ballou, Mrs. Connelly, Mr. Tomat (FCMA), and Ms. Harney (NHCMA).

Absent were: Drs. Chmieleski, Dardick, Fox, Hollister, Intravia, Lesnik, Parikh, Petro, Reyelt, Jr., Welch, and Zeppieri.

Reports of Related Organizations

M.D. Health Plan: Guy W. Van Syckle, M.D., Medical Director of MDHP, reported that the Plan has enrolled over 44,000 members and 2500 physicians, which is 28 percent over projection. The physician growth continues without any active recruit at the rate of 50-60 joining each month. He reported that there continues to be a shortage of physician participation in Danbury, New Britain, certain areas of Fairfield County and an overall shortage of pediatricians. The ambulatory care review system which was implemented in April caused a significant amount of unrest in the medical community and after two months trial, the ambulatory care review was continued but the financial sanctions were stopped. The errors and problems were varied and caused mostly by coding errors, i.e. using obsolete CPT Codes. To correct this problem, six seminars will be held throughout the state for office staffs to indoctrinate them as to how to properly code the different procedures.

He reported that there is still a problem of over utilization and it is hoped to reduce this percentage from 8%-9% to 5%. Each of the ambulatory care patterns and justification for number of visits and procedures have been reviewed by members of the IPA in the individual specialties and it is planned to reinstitute the patterns program and financial sanctions in October. A feature of the Open-ended Plan, one of the new products, will be that a participant will be able to choose a participating physician or non-participating physician for medical care. With a non-participating physician there are increased co-payments and deductibles. There is also the MED-CHOICE program whereby MDHP provides the utilization review, quality assurance and financing billing for a company's self-funded program, where MDHP receives remuneration for the administrative services rendered, and the company is at risk for their costs.

CPRO: Edward A. Kamens, M.D., stated that the PROs nationally report denials of less than 1.7% of cases and that the Connecticut incidence of adverse quality care is about one tenth of 1%, which speaks for the quality of care that is being received in Connecticut. He also reported that CPRO is currently working with the Department of Income Maintenance on the Medicaid program.

CMIC: Mehdi S. Eslami, M.D., reported that the CMIC Board is discontinuing surplus contributions for new members effective October 1, 1990. Also CMIC is eliminating the interest charge for premium installment payments. It was also reported that the premiums for professional liability insurance will be lower than the previous year and that there will be some changes in the specialty risk classifications which will result in a decrease in rates. Dr. Eslami expressed, on behalf of the physicians of Connecticut, their thanks and appreciation to the Council and House of Delegates for their foresight in creating CMIC, which moderated premiums for professional liability insurance and has become a competitive force in the market, thereby lowering rates for all practicing physicians in Connecticut.

Advance Practice Registered Nurses (APRN'S): Neil H. Brooks, M.D. reviewed a letter from Stanley H. Peck, Director of the Division of Quality Assurance of the Department of Health Services, concerning draft regulations governing Advanced Practice Registered Nurses. Dr. Brooks also discussed, in detail, each of the draft regulations outlining settings in which APRN'S may practice. It was VOTED that Dr. Brooks could conclude from the discussion that all proposed practice settings would be acceptable if regulations are tight enough to control such practice.

Report of the President

Dr. Eslami reported that he was happy to report that there were no crises during the summer. He also received a request from the CSMS-IPA Board for the names of two nominees to fill two vacancies on the Board. It was VOTED to submit the following names:

Craig W. Czarsty, M.D., Oakville, FP, (New Haven County)

Rozann F. Venti, M.D., Amston, IM, (Hartford County)

Report of the Executive Director

Mr. Norbeck reported that the AFL-CIO will be launching shortly a national TV campaign calling for national health insurance and that although the ads have not been seen yet, they will no doubt be anti-physician oriented.

He further reported that the staff has been working with Drs. Eslami and Ahamed to update the five public service pamphlets which were published about eight years ago on the subjects of health care cost, alcohol, smoking, lifestyle and nutrition. Two additional pamphlets are being added, "Knowing your Physician" and "AIDS". Some of these publications will be published in Spanish and they will represent the latest information available today on the subjects mentioned and will be a bonafide public service and also show physicians in a favorable light.

He reported that in a recent Boston Globe/Station WBZ poll the results indicated that 81% of the public think that the Massachusetts state government is out of touch with state residents. When asked "Who do you think that the Massachusetts state government serves?", the results were as follows: 3% said the poor/needy, 5% said nobody, 10% said the rich, 13% said the people, and an overwhelming 48% said the politicians.

Gubernatorial Candidates

Four gubernatorial candidates were invited to address the Council and three were able to appear. They were: Messrs. Cibes, Morrison and Rowland. Mr. Weicker was unable to attend and it was VOTED to invite him to attend the Council meeting on October 17. The candidates discussed various issues and then were available for questions.

Connecticut Nutrition Council

It was VOTED to receive, as information, a communication from the Connecticut Nutrition Council expressing their thanks to Vincent Catrini, M.D., the CSMS representative to CNC, for his strong support of CNC in carrying out their programs.

Life Member

It was VOTED to receive as information the name of the following physician who was granted Life Membership as of 1/1/90:

James L. Krieger, M.D. Ponte Vedra Beach, Florida, (H)

N.B. : *The foregoing is a summary of the proceedings and action of the Council on September 6, 1990. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for the perusal by any interested members of the Society.*

IN MEMORIAM

ANDREWS, RALPH C., Boston University, 1950. Dr. Andrews was a psychiatrist in the New London County area since 1953. He was a member of the New London County Medical Association and the Connecticut State Medical Society; died 1 June 1990 at the age of 76.

ARONS, MILTON R., University of Maryland, 1930. Dr. Arons specialized in diseases of the eye, ear, nose, and throat in the Hartford County area since 1931. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 6 August 1990 at the age of 86.

BARKER, NORMAN J., University of Toronto, 1926. Dr. Barker was a medical director in the Hartford County area since 1930. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 5 June 1990 at the age of 89.

BROWN, DAVID A., Long Island College of Medicine, 1946. Dr. Brown was a pediatrician in the Fairfield County area since 1951. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 31 May 1990 at the age of 68.

ELLIOTT, JOHN R., Boston University, 1932. Dr. Elliott was a general practitioner in the Litchfield County area since 1932. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society; died 19 July 1990 at the age of 83.

FLYNN, CHARLES T., Yale, 1943. Dr. Flynn was an orthopedic surgeon in the New Haven County area since 1950. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 11 September 1990 at the age of 72.

GRISWOLD, EDWIN M., Yale 1932. Dr. Griswold was a general practitioner in the Hartford County area since 1934. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 11 July 1990 at the age of 83.

GURA, GEORGE M., Loyola, 1931. Dr. Gura was a general practitioner in the Hartford County since 1933. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 14 August 1990 at the age of 85.

JOB, GIL G., University of Philippines, 1959. Dr. Job was a general surgeon in the New Haven County area since 1966. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 13 June 1990 at the age of 57.

JONES, MARTLING B., New York University, 1941. Dr. Jones was a general surgeon in the Fairfield County area since 1941. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 17 June 1990 at the age of 83.

LEVIN, HYMAN A., New York University, 1918. Dr. Levin was urologist in the New Haven County area since 1919. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 15 August 1990 at the age of 96.

MCQUADE, G. WILLIAM, Dalhousie University, 1963. Dr. McQuade was a general surgeon in the Fairfield County area since 1967. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 2 June 1990 at the age of 53.

MOSKOWITZ, EUGENE, Basle, Switzerland, 1937. Dr. Moskowitz specialized in physical medicine and rehabilitation in the Litchfield County area since 1981. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society; died 1 September 1990 at the age of 68.

PIOUS, WILLIAM L., Jefferson Medical College, 1932. Dr. Pious was a psychiatrist in the New Haven County area since 1933. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 9 July 1990 at the age of 84.

PROSSER, FLORENCE D., Cornell University, 1928. Dr. Prosser was a general practitioner in the Windham County area since 1929. She was a member of the Windham County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 26 July 1990 at the age of 87.

SENN, MILTON J., University of Wisconsin, 1927. Dr. Senn was a pediatrician in the New Haven County area since 1949. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died 8 June 1990 at the age of 88.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a free service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to Physician Placement Service,mConnecticut State Medical Society, 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

EMERGENCY MEDICINE

Middlesex Memorial Hospital, a 240-bed community hospital with a Residency Program in Family Practice, is recruiting a full-time medical director, and one full-time staff physician, to staff our second free-standing emergency facility owned and operated by the Hospital as a division of Middlesex Memorial's Department of Emergency Service. The facility has been approved by the State's Commission on Hospitals and Health Care to operate 12 hours a day, seven days a week, and will receive ambulances and be an integral part of the community's EMS system. It is located in a highly desirable and rapidly growing residential community approximately 20 miles from Hartford and Middletown. Physicians will be credentialled as members of the Emergency Department at Middlesex, and will have the opportunity to work extra shifts in the Emergency Department if desired. We would prefer physicians with emergency department experience and board certification or eligibility in EM, IM, or FP. The medical director will have on-site responsibility for policy development and implementation, staff, QA, etc. Highly competitive salary, plus incentive. A complete range of outstanding hospital benefits. CV's to W. Gordon Van Nes, M.D., FACEP, Chairman, Department of Emergency Services, Middlesex Memorial Hospital, Middletown, CT 06457. Telephone: 344-6691.

Full-time and part-time for urgent care center in Fairfield, CT; affiliated with community teaching hospital. Hospital privileges and teaching opportunities encouraged. Nice work setting, pleasant staff and well-educated and motivated patient population. General internal medicine, family practice or emergency medicine physicians preferred. Competitive salary, excellent benefits. Please contact John Hammel, M.D., 1055 Post Rd., Fairfield, CT 06430. (203) 259-3440.

GENERAL PRACTICE/INTERNAL MEDICINE

Physician needed for general practice or internal medicine. Location: Hilliard Bldg., Manchester, CT. Phone 1-649-4838 or 1-226-4456.

INTERNAL MEDICINE

Grove Hill Medical Center—BC/BE internist to join satellite office of 56-physician multispecialty group in Central Connecticut. Experience in women's health care preferred. University-affiliated hospital and teaching opportunities. Position available June 1991, affords opportunity for association within one of the East Coast's oldest and most respected group practices, generous salary and benefits, and earned partnership status. Interested candidates should forward CV to: Kenneth T. Johnson, M.D., CEO, Grove Hill Medical Center, 300 Kensington Ave., New Britain, CT 06051.

BC/BE Internist for private practice with coverage and guaranteed income sponsored by expanding full service hospital three hours from NYC and Boston in attractive four season community. Send CV to: Yvonne Nakashian, 115 Spencer St., Winsted, CT 06098.

Grove Hill Medical Center—BC/BE internist to join 56-physician multi-specialty group in Central Connecticut. University-affiliated teaching program. Position available June 1991, affords opportunity for association within one of the East Coast's oldest and most respected group practices, generous salary and benefits, and earned partnership status. Interested candidates should forward CV to: Kenneth T. Johnson, M.D., CEO, 300 Kensington Ave., New Britain, CT 06051.

Associate pulmonary specialist sought to work with three established, board certified pulmonologists. Opportunity to work exclusively in pulmonary medicine in Meriden-Wallingford-Southington Connecticut areas in community hospitals. Additional opportunities available in nearby facilities. Please contact Richard Smith, M.D., (203) 238-8235.

OBSTETRICS & GYNECOLOGY

Southwest Connecticut. Excellent opportunity for female/male, BC/BE, Ob/Gyns. Well established progressive practice needs a new partner to replace retiring physician. We do in-office ultrasounds, colposcopy and fetal monitoring. Located across from hospital. Send CV to: Tim Sharpe, M.D., 284 Broad St., Milford, CT 06460.

PART-TIME

Full-time and part-time for urgent care center in Fairfield, CT; affiliated with community teaching hospital. Hospital privileges and teaching opportunities encouraged. Nice work setting, pleasant staff and well-educated and motivated patient population. General internal medicine, family practice or emergency medicine physicians preferred. Competitive salary, excellent benefits. Please contact John Hammel, M.D., 1055 Post Rd., Fairfield, CT 06430. (203) 259-3440.

MD/DO: Part-time position for GP/FP/IM physician in office practice in southeastern Connecticut. Flexible hours—no weekends. Contact, New England Medical Services, 400 Bayonet St., Suite 103, New London, CT 06320. (203) 444-7156.

PEDIATRICS

BC/BE pediatrician to join two young pediatricians in growing, congenial practice in New Haven County. Full or part-time, beginning July 1991 or sooner. Affiliated with major teaching hospital. Please reply to Dr. Ellen Wolfson, 50 South Main St., Wallingford, CT 06492.

PRIMARY CARE

Occupational Health. Active occupational health center has a half-time position immediately available for a physician who is BE/BC in primary care medicine. Hours are Monday through Friday, 1:00 P.M. to 5:00 P.M., at two different sites. Very likely to be full time in future. Please contact: Allen M. Ford, M.D., 140 Grandview Ave., Waterbury, CT 06708. (203) 573-8114.

PRIMARY CARE/INTERNAL MEDICINE

Primary Care—Internist—New position, immediate opening to join Yale affiliated comprehensive health center. Yale admitting privilege and clinical faculty appointment; teaching and research roles possible. Very competitive salary. Decent on-call—one weeknight/week and one weekend/5 weeks. Five weeks vacation and personal time; one week CME. Join a young collegiate group of four physicians and two PAs. Send CV to Stephen Updegrove, M.D., Medical Director, Hill Health Corporation, 428 Columbus Ave., New Haven, CT 06519. (203) 776-9594; FAX (203) 787-5510. EOE M/F.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

ANESTHESIOLOGY

July '91. Age 31. Presently in practice. Nat'l bds. AB elig. MD, Yale University School of Medicine, New Haven, CT; Int., New York University Medical Center, New York, NY; Res., New York University Medical Center (IM) and Hospital of the University of Pennsylvania, Philadelphia, PA (ANES). Prefers group type practice. Write, Michael Silverberg, M.D., Apt. 29K, 2020 Walnut St., Philadelphia, PA 19103.

GENERAL SURGERY

Jul. '91. Age 33. Nat'l bds. AB elig. MD, SUNY at Stony Brook, Stony Brook, NY; Int., Booth Memorial Medical Center, Flushing NY; Res., Huron Road Hospital, Cleveland, OH. Prefers group or assoc. type practice in a medium to large-sized community. Write, Donna Vecchione, M.D., 27700 Bishop Park Dr., #402S, Willoughby Hills, OH 44092.

INTERNAL MEDICINE

Nov. '90. Age 38. FLEX. MD and Int., Case Western Reserve University, Cleveland, OH; Res. and Fellowship, Brown University, Providence, RI (Hem/Onc). Prefers group or associate type practice in a small to medium-sized community. Write, Peter S. Dixon, M.D., 38-1/2 Castle St., E. Greenwich, RI 02818.

Immediately available. *Cardiology.* Age 30. Presently in practice. Nat'l bds. AB cert. MD, New York University, New York, NY; Int., Res., and Fellowship, Dartmouth, Hanover, NH. Prefers solo or group type practice in a medium-sized community. Write, Daniel G. Dadourian, M.D., 14 Maple Terrace, West Roxbury, MA 02132.

June '91. *Pulmonary.* Age 31. Nat'l bds. AB cert. MD, Autonomous University of Guadalajara, Guadalajara, Mexico and Mount Sinai School of Medicine, New York, NY; Int. and Res., Mount Sinai Services, Elmhurst City Hospital, Queens, NY; Fellowship, New York Medical College, Westchester County Medical Center, Valhalla, NY. Prefers group type practice. Write, Mitchell K. Rosen, M.D., 444 East 86th St., Apt. 33C, New York, NY 10028.

INTERNAL MEDICINE/FAMILY PRACTICE

Immediately available. Age 31. Licensed in Connecticut. MD, Universidad del Noreste, Tampico, Mexico; Fifth Pathway, (NYU) Booth Memorial Medical Center, Flushing, NY; Int. and Res., Flushing Hospital and Medical Center, Flushing. Prefers ambulatory care/office based type practice in a medium-sized community. Write, William M. DiFederico, M.D., 324 Sunnybank Ave., Stratford, CT 06497.

OPHTHALMOLOGY

Sept. '90. Age 37. Licensed in Connecticut. Nat'l bds. MD, University of California, San Francisco, CA; Int. Kaiser Foundation Hospital, San Francisco (IM); Res., University of California, San Francisco (OPHTH); Fellowship, Massachusetts Eye & Ear Informary, Boston, MA (OPHTH). Write, CSMS, c/o MP/OPHTH.

PSYCHIATRY

Immediately available. Age 49. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD, Osmania Medical College, Osmania University, Hyderabad, Andhra, India; Int., Osmania General Hospital, Hyderabad; Res., Manchester University, England; Fellowship, William S. Hall Institute of Psychiatry, Columbia, SC. Prefers part-time positions. Naimetulla A. Syed, M.D., Box 5525, Fairfield Hills Hospital, Newtown, CT 06470.

PAID CLASSIFIED ADVERTISING

All paid classified advertising orders, correspondence and payments should be directed to : CONNECTICUT MEDICINE, Classified Department, 160 St. Ronan St., New Haven, CT 06511, Tel. (203) 865-0587. The classified rates are as follows: $60.00 for 25 words or less; plus $1.00 for each additional word. For confidential answers, the cost is $3.00 per insertion, sent in care of CONNECTICUT MEDICINE. Ad copy, with payment, must be received no later than the first day of the month preceding month of issue.

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Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatric. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

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How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
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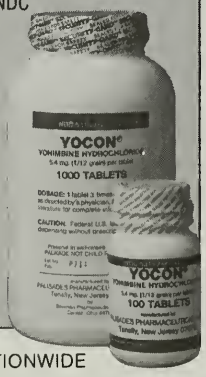

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Bronchial Hyperresponsiveness in Asthma: Its Significance and Therapy

RICHARD L. ZUWALLACK, M.D.

Introduction

A recent definition of bronchial asthma includes the presence of bronchial hyperresponsiveness (BHR) as well as intermittent symptoms of wheeze, chest tightness, and cough.[1] BHR, which is best determined by provocation testing, is arguably the most important feature of asthma. It describes the airways' marked readiness to reduce their caliber in response to a wide variety of specific and nonspecific provocative stimuli. Clinical manifestations include exercise-induced bronchospasm, irritant fume induced asthma, bronchospasm following allergen inhalation, and an exaggerated circadian decrease in early morning airflow.

Virtually all symptomatic asthmatics have BHR demonstrated by bronchoprovocation testing.[2] Inhalation challenge test abnormalities indicative of BHR have also been described in other conditions, such as allergic rhinitis,[3] chronic obstructive pulmonary disease,[4] cystic fibrosis,[5] sarcoidosis,[6] bronchiectasis,[7] and even congestive heart failure.[8] The frequency and magnitude of BHR in these conditions, however, is less than in symptomatic asthma.

Although BHR has received much deserved attention over the past decade, confusion exists between the terms hypersensitivity, hyperreactivity, and hyperresponsiveness. Hypersensitivity indicates a lower stimulus threshold for bronchoconstriction, and hyperreactivity an exaggerated decrease in airway caliber to a provocative stimulus. The term hyperresponsiveness encompasses both and will be used in the remainder of this paper. Specific hyperresponsiveness refers to the propensity to develop airways obstruction following inhalation of a specific stimulus, such as an allergen. This phenomenon occurs only in those allergic asthmatics sensitized to the particular inhalant. Nonspecific hyperresponsiveness, on the other hand, refers to airways obstruction brought on by a provocative stimulus that affects virtually all asthmatics. Nonasthmatics usually have either an absent or a significantly lesser response to these stimuli. It is this nonspecific BHR which is universal in the symptomatic asthmatic population and will be the main focus of this paper.

Measurement of Bronchial Hyperresponsiveness

Various laboratory techniques are available for the determination of BHR,[9] including cold air hyperventilation, exercise, and inhalation challenge with methacholine (a cholinergic agonist), histamine, or an ultrasonically nebulized fog of distilled water. Despite differences in methodology, all are capable of determining the presence and degree of BHR. BHR is estimated by measuring the concentration or amount of the provocative stimulus required to produce a specified degree of airways obstruction: the lesser the provocative stimulus, the greater the BHR. Airways obstruction is usually determined by obtaining successive measurements of the forced expiratory volume in one second (FEV_1) following increasing doses of the provocative agent.

Two principal techniques of aerosol generation and inhalation currently used have been compared by Ryan et al,[10] and found to have similar results and reproducibility. One technique requires the subject inhale for two-minute periods increasing concentrations of histamine or methacholine until the FEV_1 drops by 20% or more from its baseline value, or until a predetermined maximum concentration is reached. The provocative concentration that leads to the 20% reduction in FEV_1 is called the PC_{20}. The other technique involves inhalation of an increasing number of doses of the provocative agent until the FEV_1 drops by 20% from the baseline. This dose is called the PD_{20}. Asthmatics are 100 to 1,000 times more sensitive than normals to these provocative agents.[11]

It should be emphasized that the presence of an abnormally low PC_{20} indicates a lower threshold to stimulation, with a shift of the dose-response curve (ie, hypersensitivity). This is not strictly equivalent to the biologic process, BHR, which also encompasses hyperreactivity.[12] Not only is the provocative threshold for developing airways

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obstruction lower in asthma, the dose-response curve, which reflects hyperreactivity, differs from normals. Asthmatics have a steeper dose-response curve to the provoking agent (ie, hyperreactivity), and actually differ more strikingly from normals in this slope than in their response threshold.[13] Furthermore, asthmatics usually do not reach a plateau of airways obstruction with increasing concentrations of the inhalant whereas normal subjects usually do.[14] This inability to reach a response plateau suggests asthmatics lack an inhibitory mechanism to turn off bronchospasm.

Bronchial Hyperresponsiveness in Asthma

The BHR that is so characteristic of asthma may precede the development of clinical asthma by a considerable period of time. A recent paper by Hopp and others[15] described a group of 13 children and young adults who were first studied 3.5 years before a diagnosis of clinical asthma was made. Ten had moderate or strongly positive methocholine inhalation challenges on the initial visit, indicating that BHR precedes the development of asthma.

Despite almost universal occurrence, considerable variation in the degree of BHR exists in the asthmatic population. For example, although Cockcroft and others[2] found a reduced PC_{20} to histamine in all of a large group of asthmatics requiring medications, this varied in degree from less than 0.125 mg/ml to almost 8 mg/ml. This marked intersubject variation in sensitivity probably reflects differences in disease severity. Despite this considerable intersubject variation, BHR is said to remain relatively stable over long periods of time.[16] A recent, serial evaluation of individual asthmatics, however, has disclosed more variability than originally believed.[17] Some of this variation undoubtedly reflects day to day increases in BHR over baseline resulting from such triggering circumstances as upper respiratory infections, or inhalation of irritants or allergens.

Interestingly, while some exposures produce prolonged increases in BHR, others result in transient bronchospasm without a sustained increase in BHR. The former, since they enhance BHR, have been called "causative triggers," while the latter have been named "symptomatic triggers."[18] Causative triggers include: the allergen-induced late asthmatic response,[19] certain low molecular weight sensitizing chemicals such as toluene diisocyanate[20] or western red cedar,[21] viral respiratory tract infections,[22-24] and exposure to oxidizing pollutants such as ozone[25] or nitrogen dioxide.[26] Even seasonal pollen can increase BHR in nonasthmatics with allergic rhinitis, although not to a degree as to cause bronchospasm.[27] The central feature shared by all these stimuli is their capacity to cause airway inflammation or epithelial damage. Symptomatic triggers, on the other hand, probably do not produce significant acute airway inflammation or epithelial damage. These triggers include such stimuli as exercise, cold air inhalation, the early asthmatic response following allergen inhalation, low concentrations of irritants such as cigarette smoke, and histamine or methacholine.[18]

Bronchial Inflammation in Asthma: Its Relationship to Hyperresponsiveness

Although the presence of airway inflammation in bronchial asthma was appreciated in the last century,[28] most attention focused on the nature and treatment of bronchospasm. Recently, however, the importance of inflammation and its major role in the pathogenesis of BHR has emerged.[29] Inflammation is present in severe asthma,[30] and qualitatively similar changes are present on biopsy or bronchoalveolar lavage of milder cases, as well.[31-33] The submucosa is so infiltrated with eosinophils that one author[34] has used the description, chronic eosinophilic bronchitis, to describe this disease. Denudation of the bronchial epithelium, exposing a thickened basement membrane is another prominent feature of asthma.[33] This epithelial disruption exposes submucosal vagal afferent C-fiber nerve endings to inflammatory mediators, and thereby may enhance BHR through an augmented axon reflex.[35]

The importance of cellular infiltration in the disease was underscored by Wardlaw and associates[36] who did bronchoalveolar lavage in four groups of patients: symptomatic asthmatics, asymptomatic asthmatics, nonasthmatics with allergic rhinitis, and nonallergic controls. Both asthmatic groups had a significantly greater percentage of mast cells recovered from bronchoalveolar lavage than the nonasthmatics. Also, the symptomatic asthmatics, compared to nonasthmatics, had a greater percentage of eosinophils along with a greater amount of their cytotoxic granule protein, major basic protein. In addition, the symptomatic asthmatics had a greater percentage of epithelial cells on bronchoalveolar lavage than normoreactive asthmatics and nonasthmatics. Finally, an inverse correlation was found between the PC_{20} and the percentage of mast cells, eosinophils, and epithelial cells, and in the amount of major basic protein in the lavage fluid. A subsequent investigation by Ferguson and Wong[37] also showed a correlation between BHR and increased counts of eosinophils and macrophages in asthmatic children.

A recent study by James and coworkers[38] compared the postmortem airway findings of 18 asthmatics with those of 23 nonasthmatics. The asthmatics' airways showed significant inflammatory cell infiltration, basement membrane thickening, mucus gland and goblet cell prominence, and partial luminal occlusion with mucus and cellular debris. The epithelial, muscle, and submucosal inflammation were all responsible for the measured increase in wall area of both large and small airways. This airway thickening caused by chronic inflammation was possibly as important as smooth muscle shortening in determining airway caliber.

The airway inflammatory response, with its augmentation of BHR, may have a nonallergic as well as an allergic basis. For example, inhalation of ozone leads to an influx of neutrophils into alveoli and small airways. The presence of these neutrophils, which may be recovered on broncoalveolar lavage, coincides with an increase in BHR.[25] Allergic airway responses, likewise, may produce significant inflammation. In the allergic asthmatic, a single allergen inhalation frequently leads to two periods of airways obstruction: the early asthmatic response (EAR) and the late asthmatic response (LAR).[39] The EAR appears within several minutes of exposure and is usually transient and readily treatable. This is followed at least 50% of the time by the LAR, more prolonged and less readily reversible episode of airways obstruction occuring several hours later. The LAR, but not the EAR, is responsible for the prolonged increase in nonspecific BHR noted to be present after some allergen inhalations.[19] Bronchoalveolar lavage fluid obtained at the time of the LAR has increased eosinophils and increased concentrations of their cytotoxic mediator, eosinophilic cationic protein,[40] a finding suggesting the LAR's effect on BHR is mediated through recruitment of inflammatory cells.

Hyperresponsiveness and Asthma Severity

The relationship between BHR and indices of asthma severity including symptoms, medication requirements, and diurnal fluctuation in airflow has become well recognized. As early as 1966, Makino[41] described a relatively weak, although statistically significant, negative correlation between threshold sensitivity to inhaled acetylcholine and an estimate of the previous year's asthma severity. Murray[42] showed a similar relationship, where asthmatics with a greater degree of BHR as estimated by cholinergic inhalation challenge were more symptomatic. Other investigators have shown a positive relation between BHR as measured by inhalation challenge and degree of exercise-induced bronchospasm[43] or severity of specific antigen challenge.[44]

In 1975, Spector and Farr[45] reported that hospitalized asthmatics with a greater degree of BHR required more corticosteriod treatment upon discharge. A later investigation[46] of 243 hospitalized asthmatics found those with lower methacholine or histamine responsiveness had a longer duration of asthma, developed clinical symptoms sooner, and were admitted to the hospital at an earlier age than those with greater responsiveness. Since pulmonary function tests were not significantly different between the two groups, BHR may influence symptomatology independently of an effect on baseline airflow obstruction.

Cockcroft and associates[2] showed a close association between the severity of BHR and treatment requirements for asthma. In this investigation, BHR was divided into mild ($PC_{20} > 1$ mg/ml and < 8 mg/ml), moderate (0.125 to 1 mg/ml), and marked (<0.125 mg/ml). Most patients with mildly increased BHR required bronchodilators only occasionally, those with moderately elevated BHR required the regular use of bronchodilators, while those with severely increased BHR required corticosteroids.

BHR is also related to morning peak expiratory flow rate, improvement in airflow following bronchodilator inhalation, and diurnal fluctuation in peak flow in asthma.[47] This relationship is important since increased diurnal fluctuation in airflow may be related to asthma severity and even to asthma mortality.[48]

The contribution of BHR to the day-to-day expression of bronchial asthma was elevated by Josephs and coworkers[49] in a recent study. Responsiveness to methacholine was measured every two to three weeks over a 12-to 18-month period. Although they found a significant relation of the degree of BHR with the day-to-day and diurnal variation in peak expiratory flow measurements, individual PC_{20} measurements were not consistently related to asthma severity as measured by symptoms.

Treatment of Bronchial Hyperresponsiveness

General

Asthma therapy may be divided into two categories: 1) that which improves bronchoconstriction but does not appreciably affect baseline BHR, and 2) that which leads to a sustained improvement in BHR.[18] The three classes of bronchodilators, theophylline, beta-adrenergic agents, and anticholinergic agents, although mainstays in the symptomatic treatment of asthma, have only transient effects on BHR, and thus fall into the first category.

Therapeutic serum levels of theophylline or the new xanthine derivative, enprofylline, cause a modest, acute improvement in histamine-induced bronchoconstriction.[50-52] Little information is available, however, concerning a sustained reduction in baseline BHR with chronic use of this drug.[51]

Inhaled beta-adrenergic drugs have a substantial albeit short-term effect in decreasing BHR,[50,53] an effect which is probably greater in magnitude than that of theophylline.[50,52] Interestingly, this beneficial effect on BHR is of shorter duration than the bronchodilating effect, a phenomenon which may be important clinically.[53] Like theophylline, no convincing effects of long-term beta-adrenergic therapy on baseline BHR have been shown. Thus, Peel and Gibson[54] were not able to demonstrate a beneficial effect of four weeks' salbutamol treatment on histamine provoked bronchoconstriction despite significant improvement in airflow. One study, in fact,[55] showed a slight increase in BHR with terbutaline use.

Even less is known about the effect of anticholinergics on BHR than for the above two classes of bronchodilators. Inhalation of the anticholinergic drug, ipratropium, before inhalation challenge caused a marked decrease in responsiveness to the cholinergic agonist, methacholine, in a study by Bandouvakis and associates.[56] Its ability to block histamine-induced airways obstruction was only marginal, however. After correction for the change in baseline FEV_1, this effect was neither statistically significant nor as great in magnitude as that of the beta-agonist, fenoterol. A recent, double-blind, randomized, parallel study comparing the long-term effect of ipratropium and fenoterol on histamine bronchoprovocation in asthmatic children failed to show any sustained effect on BHR by either drug.[57]

It is reasonable to conclude that conventional bronchodilator use improves asthma symptoms but does little to improve the underlying asthmatic state since it has minimal long-term effect on baseline BHR. Other drugs, such as ketotifen,[58,59] inhaled solutions of the antihistamines, azelastine, [59,60] and terfenadine,[61,62] and inhaled calcium channel blockers[63] may reduce responsiveness when given prior to provocative stimuli. Any long-term improvement in BHR resulting from their use, however, remains questionable. Other therapies, including allergen avoidance, hyposensitization, and treatment with nedocromil, corticosteroids, and cromolyn, through their salutary effect on BHR may actually reduce baseline asthma severity.[18,64]

Allergen Avoidance and Hyposensitization

As described earlier, the allergen-induced LAR may cause a long-term increase in BHR, probably because of the development of bronchial inflammation. Decreasing the frequency of the LAR through allergen avoidance may reduce baseline BHR in allergic individuals. To test this hypothesis, Dorward et al[65] evaluated allergen avoidance measures on BHR and airflow in a group of nine mildly asthmatic patients with positive skin tests to the European house dust mite, *Dermatophagoides pteronyssinus*. Measures included soaking mattresses and bedroom carpets with liquid nitrogen, weekly vacuuming of beds, cleaning blankets, pillows, sheets and pillow cases, and removal of plants, soft toys, cushions, and upholstered furniture from the bedroom. At eight weeks this avoidance group not only had significant improvement in symptoms as compared to a control group, but also their BHR improved significantly, with the PC_{20} to histamine increasing from 0.58 to 2.3 mg/ml. This improvement in BHR occurred without a significant increase in the FEV_1. Other studies have also shown improvement in BHR with avoidance of allergen.[66,67]

A comprehensive review of allergen immunotherapy in allergic asthma by Ohman[67] found 13 controlled studies that evaluated the effect on BHR of this form of therapy. Hyposensitization was to mixed grasses, ragweed, house dust, *Dermatophagoides pteronyssinus*, cat and dog dander, and the mold *Cladosporium herbarum*. Ten of the 13 studies demonstrated some beneficial effect on bronchoconstriction during provocation tests, suggesting that hyposensitization has a role in favorably modifying BHR in selected allergic asthmatics.

Cromolyn Sodium

Although it is not a bronchodilator, cromolyn sodium is an effective medication in allergic and nonallergic asthmatics, probably through its prevention of mediator release.[69,70] Bronchospasm brought on by exercise,[71] cold air hyperventilation,[72] sulfur dioxide,[73] and both the EAR and LAR induced by antigen inhalation[74] are blocked by this drug. This inhibition of the LAR appears responsible for its effect on reducing baseline BHR in allergic asthmatics.[74] As early as 1967, Altounyan[75] reported that cromolyn use decreases histamine-induced BHR. More recently, Lowhagen and Rak[76] compared the effect of cromolyn treatment in 10 birch pollen-sensitive asthmatics with 12 controls. Histamine inhalation tests were performed at baseline, two, four, and six weeks from the beginning of birch pollen season. In the control group, BHR increased significantly at the height of pollen season and returned to baseline levels after the season was over. The cromolyn treated group, although it did not show improvement in BHR, did not have the seasonal increase shown by the control group. This favorable effect on BHR during seasonal asthma has been shown by others as well.[77,78]

A subsequent investigation by Laitinen and coworkers[79] of 14 adult asthmatics in cold, pollen-free winter months failed to demonstrate any changes in histamine-induced BHR with four weeks of cromolyn treatment, suggesting that this drug does little to affect baseline BHR in patients not exposed to antigenic stimulation. Based on this, it is likely that cromolyn's greatest usefulness is in preventing temporary increases in BHR brought on by allergen inhalation. This prophylactic effect of cromolyn has been likened to that of environmental control.[18] A recent study,[70] however, did show significant improvement in methacholine BHR over its baseline in 68 chronic asthmatics, suggesting that long-term cromolyn treatment may improve baseline BHR in a heterogenous group of asthmatics not necessarily studied during seasonal antigenic stimulation.

Nedrocomil Sodium

Nedrocomil sodium is a new antiasthma drug which may work through inhibition of eosinophils and other effector cells when they are stimulated.[80] Studies have shown a single-dose, protective effect in exercise-induced asthma.[81,82] Perhaps more importantly, long-term treatment has recently been shown to improve methacholine-induced BHR in a group of nonsteriod-dependent, nonatopic asthmatics.[83] This beneficial effect on BHR, which took four weeks to appear, differed from that of the inhaled corticosteroid, beclomethasone, in that it was not accompanied by an improvement in airflow.

Corticosteroids

In 1982 an uncontrolled study by Clarke[84] demonstrated a small but statistically significant improvement in histamine reactivity over baseline in a group of 14 asthmatics treated for several weeks with inhaled beclomethasone. That same year, Juniper, Frith, and Hargreave[85] showed an increase in histamine-induced PC_{20} from 0.50 to 1.23 mg/ml in 15 adult asthmatics treated with beclomethasone for periods ranging from 10 to 30 months. This improvement in BHR correlated with improvement in FEV_1. Shortly afterward, Ryan and associates[86] reported that four weeks of inhaled beclomethasone produced a small increase in histamine-induced PC_{20} in 10 asthmatics, although it was of little clinical significance.

In 1987 Kerrebijn and associates[87] showed that six months' treatment with budesonide, a potent inhaled corticosteriod, reduced methacholine-induced BHR in mildly-affected asthmatic children, while a terbutaline-treated group had no such improvement. The asthma was of mild severity throughout the study and there was no correlation between change in BHR and change in FEV_1, indicating improvement in BHR was not due to decreased airways obstruction. This latter finding contrasts with the findings of Juniper. Svendsen et al,[88] from Copenhagen, showed a significant increase in PC_{20} to histamine in adult asthmatics treated for eight weeks with inhaled beclomethasone.

In a double-blind crossover study, Dutoit, Salome, and Woolcock[89] compared the effect of 800 mcg of inhaled beclomethasone per day to oral theophylline on histamine BHR in 14 asthmatics. By four weeks, the geometric mean PD_{20} of the steroid group improved from 0.09 umol to 0.63 umol, which is equivalent to improvement from a severe to a moderate range. In four of the 14, however, it remained essentially unchanged and in the severe range. Continuing the beclomethasone treatment for 10 weeks did not increase the PD_{20} further. The theophylline treated group had no significant alteration in their degree of BHR. There was no concomitant increase in FEV_1 in either group. Again, there was a significant relationship between the initial degree of BHR and FEV_1 values, leading the authors to conclude that the relationship exists only in the presence of relatively severe airflow obstruction.

Krann et al[90] showed improvement in methacholine-induced PC_{20} in 30 allergic asthmatics taken off their regular asthma medications and treated with inhaled budesonide. This dose-dependent effect on BHR was noticeable at two weeks, and by eight weeks the PC_{20} to methacholine tripled from 0.91 to 2.74 mg/ml. Recently, ZuWallack et al[91] showed an almost three-fold increase in methacholine-induced PC_{20} in asthmatics treated with the inhaled corticosteroid, triamcinoline. Furthermore, a subgroup with higher medication compliance increased their PC_{20} by 533% versus a 68% increase in those with lower compliance.

Interestingly, and somewhat paradoxically, moderate doses of oral corticosteroids, although undeniably beneficial in asthma therapy, are not as well established for a role in reducing BHR as their inhaled counterparts. In 1984, Sotomayor[92] showed that six days' treatment of 10 pollen-allergic asthmatics with 16 mg methylprednisolone reduced their seasonal increase in BHR back to baseline. Mattoli and associates,[93] however, were not able to demonstrate a favorable effect on either high-dose intravenous methylprednisolone on BHR measured eight hours after the dose, or of daily administration of 32 mg of this drug, with BHR measured eight days after the start of therapy. Recently, Jenkins and Woolcock[94] showed that inhaled beclomethasone, but not a dose of 12.5 mg prednisone given orally, improved BHR at three weeks despite similar improvement in airflow.

Summary

BHR is a characteristic, almost universal feature of bronchial asthma. Easily measured in the laboratory with bronchoprovocation testing, its magnitude correlates with the severity of asthma. Bronchial inflammation, an integral part of asthma, is believed to be important in the pathogenesis of BHR. Certain asthma triggers, such as the LAR, exposure to some low molecular weight substances such as toluene diisocyanate or western red cedar, respiratory tract infections, and oxidizing pollutants may cause prolonged increases in BHR. When given immediately before a provocative stimulus, bronchodilators have only a short-term beneficial effect on BHR. Other therapies, however, including allergen avoidance and hyposensitization therapy, and drug treatment with cromolyn sodium, nedocromil or corticosteroids may favorably modify BHR and thereby improve the underlying asthmatic state. These drugs may work in part through their inhibition of the LAR and its subsequent increase in nonspecific BHR. Cromolyn works prophylactically in preventing allergen-induced increases in BHR. Nedocromil, a new antiasthma drug which inhibits eosinophils and other effector cells, has recently been shown to modify baseline BHR favorably in nonsteroid dependent, nonallergic asthmatics. Inhaled corticosteroids, which reduce airway inflammation, have a favorable effect on baseline BHR in both allergic and nonallergic asthmatics.

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Surgical Management of Lithium-Induced Hypercalcemia

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Introduction

The development of lithium-induced hypercalcemia is a side effect of clinical significance.[1] This condition can be managed by either discontinuing lithium treatment or by focusing attention on the management of the hypercalcemia. The frequency and intensity of the manic-depressive episodes must be weighed against sequela and severity of the hypercalcemia caused by the lithium.[2]

The following case study reports a 10-year follow-up of a manic-depressive patient with lithium-induced hypercalcemia treated by a subtotal parathyroidectomy. The surgical procedure resulted in a correction of the hypercalcemia while maintaining adequate lithium blood levels for mental well being.

Case Report

A 72-year-old white female presented with a 20-year history of manic-depression. From 1977 to 1980 she was well controlled and was taking lithium carbonate, 900 mg daily. Therapeutic serum lithium levels ranged between 0.8 and 1.2 mg/dL. During a routine visit a serum calcium of 12.3 mg/dL (normal 8 - 10.5) was found. The serum parathyroid hormone was 920 pg/ml (normal 100-600). Lithium carbonate therapy was discontinued and the serum calcium level returned to normal. A reappearance of bouts of agitation, hyperargumentativeness, and depression occurred. During this lithium-free period, serum calcium levels were below 10.5 mg/dL and the parathyroid hormone about 400 pg/ml. The manic-depressive episodes became unmanageable and lithium carbonate was reinstituted. Again, an increase in serum calcium levels as high as 11.3 mg/dL was observed. It was recommended by several consultants that lithium maintenance be continued and that the parathyroids be explored. At the time of surgery, all four glands were identified and appeared to the senior author as being enlarged. Three and one-half glands were removed. Histologic examinations revealed chief-cell hyperplasia. Postoperatively the serum calcium levels were recorded as low as 7.5 mg/dL. This was associated with a normal parathyroid hormone level. There followed a gradual increase of serum calcium levels to 8.0 - 9.0 mg/dL. Following surgery, the patient has been maintained on lithium carbonate. Over the past ten-year period her serum lithium levels have ranged from 0.7 - 1.0 mg/dL and have been associated with normocalcemia. Her mental status examination throughout this period has been stable without any major psychiatric complaints.

Discussion

Lithium salts were approved for treatment of manic-depression in the United States in 1970.[3] Several years later the first reported case of lithium-induced hypercalcemia appeared.[4] In a review of the literature, the incidence of this adverse effect of lithium therapy has been estimated to be about 10%.[5] More recent studies have investigated the effects of lithium on calcium metabolism.[6,7] Current hypotheses suggest that lithium directly affects parathyroid function and growth.[8] In vitro studies demonstrate that lithium-induced higher serum calcium concentration inhibits parathyroid hormone secretion.[9] By altering the "set point" or calciostat" a clinical picture of hyperparathyroidism is created.[10] Prior reports of lithium-induced hypercalcemia, in which parathyroid tissue was examined, revealed the presence of a single adenoma in 11 cases and hyperplasia in one.[4,11-16] The occurrence of nodular chief-cell hyperplasia in all four parathyroid glands supports the hypothesis that long-term lithium maintenance may adversely stimulate parathyroid growth and function. In as much as lithium affects the chief cells of the parathyroid gland, a major physiologic regulator of serum ionized calcium, hyperparathyroidism may result.

Although lithium carbonate is the accepted drug for treatment of bipopular disorders, alternative antimanic-depressive treatments may be effective and should be considered with the appearance of lithium-induced hyperparathyroidism.[17] If the serum calcium levels are only slightly elevated and the lithium-treated patient is asymp-

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tomatic, conservative follow-up every three months is advised. When serum calcium levels approach 11 mg/dL the following management scheme seems appropriate:

1. A serum calcium above 11.0 mg/dL should be closely followed and, if persistent, a the serum parathyroid hormone level is determined. A relatively elevated parathyroid hormone level in such cases indicates the presence of increased parathyroid function.[18]
2. In order to determine whether the above biochemical abnormalities are reversible, lithium carbonate should be discontinued. This helps to establish the etiology of the hypercalcemia.[19,20]
3. Lithium withdrawal should result in a recurrence of the manic-depressive symptoms as well as a fall in serum calcium levels. In addition, the recurrence of the bipopular disorder should be refractory to alternative medical treatment, necessitating reinstituting lithium carbonate maintenance. A rise in serum calcium and parathyroid hormone should again be observed.
4. Finally, if all of the above criteria are met, parathyroid exploration should be considered.

The management of the asymptomatic hypercalcemia, although still a matter for debate, favors surgical intervention.[21,22] The early prevention or correction of the sequela of hypercalcemia, namely the psychologic manifestation, cardiovascular effects, gastrointestinal disorders, bony changes, and kidney complications, must be weighed against the psychosocial problems and morbidity associated with the uncontrolled manic-depressive patient. The present consensus is that surgery is the treatment of choice when the diagnosis of hyperparathyroidism secondary to lithium maintenance is firmly established, when the surgery carries a low operative risk and when an experienced parathyroid surgeon is available.[23-25]

Conclusion

The sequellae of lithium induced hypercalcemia may create a therapeutic dilemma in the treatment of the manic-depressive patient.

A 10-year follow-up of a manic-depressive patient who underwent a subtotal parathyroidectomy to correct lithium-induced hyperparathyroidism is the subject of this report. This case appears to confirm the impression that lithium stimulates parathyroid mass and function.

The specific criteria that should be met before advising parathyroidism in the manic-depressive patient are presented. The merits of maintaining lithium treatment of a manic-depressive patient while at the same time surgically correcting the lithium-induced hypercalcemia appears to be an option warranting serious consideration.

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Cystosarcoma Phyllodes: Is Local Excision Enough?

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Introduction

CYSTOSARCOMA phyllodes is a rare breast tumor first described by Johannes Muller in 1838. It constitutes only 1% of all breast neoplasms.[1] It is similar to a fibroadenoma in structure, but is distinguished from a fibroadenoma by virtue of its stromal hyperplasia of fibroblasts. Clinically, cystosarcoma phyllodes is distinguished from fibroadenoma by its sometimes malignant course, occurring in less than 10% of cases.[2] Histological differentiation of benign and malignant disease remains unclear. The primary treatment of cystosarcoma phyllodes is surgical. The extent of surgery necessary to effect cure remains unclear. Removal of the tumor, wide local excision, simple mastectomy, modified radical mastectomy, and radical mastectomy have all been advocated as treatment of this disease. The recent literature has advocated more limited procedures for cystosarcoma phyllodes. The following study was undertaken to determine if local excision is adequate treatment for cystosarcoma phyllodes.

Material and Methods

Prior to 1975 cystosarcoma phyllodes was not classified by the tumor registry at Waterbury Hospital. Therefore, all tumor registry records of patients with cystosarcoma phyllodes after this time were reviewed. There were eight patients operated on for cystosarcoma phyllodes during this 14 year period (1975 - 89). The tumor registry records of these patients were reviewed for demographic characteristics, pathology, treatment, and eventual survival. The type of treatment was determined from the surgeon's operative report. Follow-up data were obtained by contacting the surgeon's office.

The diagnosis of cystosarcoma phyllodes was confirmed by the senior pathologist reviewing each case. Each case was rereviewed histologically with attention to the gross and histologic criteria: tumor size, cellularity, and atypicality of the stroma. In addition, the presence or absence of stromal overgrowth, as defined by Ward and Evans,[3] was ascertained. These authors defined stromal overgrowth as the disproportionate proliferation, at least focally, of the stromal component of the neoplasm to the exclusion of ductal components so that at least one 40x low-power field contained no ductal epithelium.

Results

All eight patients were female; their mean age was 50 years, with a range from 19 to 91 years; all patients were white.

Histopathologically there was a total of 10 tumors for review. Two patients had bilateral cystosarcoma phyllodes, one of whom had malignant tumors, and the other benign. The mean tumor size was 6.25 cm, ranging form 2.3 to 25 cm. There was one case of "giant cystosarcoma phyllodes." Seven of the tumors were classified as benign, and three as malignant. The following histologic criteria were found only in malignant tumors: frequent mitotic figures, atypicality of the stromal cells, and stromal overgrowth. Two of the three tumors classified as malignant contained areas of tumor necrosis.

The initial treatment for nine of the 10 tumors was local excision. The patient with the giant cystosarcoma phyllodes underwent a modified radical mastectomy. No axillary nodes contained tumor. Three of the tumors recurred, and all of the recurrences were from tumors originally classified as benign, and all recurrences were benign. Recurrences occurred in two patients after two months and in the other patient after 20 months. One patient underwent a simple mastectomy involving an extended local excision, ie, removal of the tumor along with a surrounding margin of grossly normal tissue.

The three malignant tumors were treated by local excision. There have been no recurrences after 90 and 26 months and both patients are alive with no evidence of metastatic disease.

Follow-up data were available on seven of the eight patients, all of whom are alive with no evidence of dis-

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ease. The eighth patient was treated in 1978, followed for 72 months with no evidence of disease, and subsequently lost to follow-up. The mean survival time of the seven patients with follow-up to the present has been 67 months, with a range from four to 142 months.

Discussion

The treatment of cystosarcoma phyllodes remains controversial. The controversy stems from the presence of a malignant variant of the disease, occurring in 10% to 30% of cases; the tendency for local recurrence of both the benign and the malignant variant; and the difficulty in distinguishing the malignant from the benign variant. The reported incidence of local recurrence ranges form 7.5%[4] to 58.8%.[5] Local excision, wide local excision, simple mastectomy, modified radical mastectomy, and radical mastectomy have all been proposed as primary treatment for cystosarcoma phyllodes.

Treves and Sunderland[6] attempted to classify benign and malignant variants in their review of 77 cases. They concluded that the best criterion for malignancy was the presence of focal subepithelial stromal cellularity and anaplasia. Lester and Stout[7] attempted to apply these criteria to their 58 cases, and found only two of their five metastasizing tumors could be classified as malignant by these criteria. Norris and Taylor[8] reviewed 94 cases of cystosarcoma phyllodes, and found infiltrating margins as opposed to pushing margins, mitotic activity greater than two mitotic figures in 10 high-power fields, and moderate to higher degrees of cellular atypism all correlated to some degree with malignant behavior. They concluded that no single feature was entirely reliable for making a clearcut separation between benign and malignant disease. Bilchert-Toft et al[5] used the criteria of dense stromal cellularity, variation in cellularity, more than moderate pleomorphism of stromal cells, coarse structure of the nucleus, and especially increased mitotic activity with the appearance of abnormal mitotic figures to define malignancy. Four of six originally benign tumors recurred and showed malignant features at the time of recurrence. Three of five patients who died of metastatic disease had tumors originally classified as benign.

More recently, Ward and Evans,[3] in a review of 26 cases of cystosarcoma phyllodes, found that stromal overgrowth was the only histologic feature that significantly correlated with metastases and tumor death. Stromal overgrowth, however, did not correlate with local recurrence. In fact, no gross or histologic feature was found to predict local recurrence. Hines et al[9] looked at numerous tumor characteristics, including tumor necrosis, infiltrating margins, increased cellularity, vascularity, mitotic figures, and pleomorphism, and found no criteria as truly reliable predictors of malignancy. In the present study, frequent mitotic figures, atypicality of the stromal cells, and stromal overgrowth were found only in those tumors classified as malignant. Neither patient with malignant disease has had a recurrence, and both are presently alive 26 months and 107 months after diagnosis. Also in the present series, no case of originally benign cystosarcoma phyllodes recurred as the malignant variant. It has been proposed that the presence of metastases represents the definitive criterion for malignancy.[10]

Because of this difficulty in predicting malignant behavior of cystosarcoma phyllodes, recommendations regarding treatment have remained controversial. Most authors have argued that wide local excision, ie, removal of the tumor with a surrounding margin of normal tissue, is adequate therapy even for recurrent disease. Others have argued that more aggressive therapy is necessary because of the risk of recurrent disease with malignant features. In the present study, all benign tumors except in the one case of giant cystosarcoma phyllodes, were treated by wide local excision. All recurrences were benign, and two of the three were treated by wide local excision.

The treatment of malignant cystosarcoma phyllodes is even more controversial. Treves and Sunderland[6] recommended radical mastectomy as the treatment of choice. McDivit et al[11] found no difference in survival when patients were treated by wide local excision or radical mastectomy. The value of lymphadenectomy as part of the surgical procedure is unproven. Haagensen[12] argued that axillary dissection is unnecessary because these tumors almost never metastasize to axillary lymph nodes. There have been rare reports of axillary node metastases but their significance with regard to indicating malignant behavior remains uncertain. In the present series only one patient had an axillary node dissection, and all nodes were negative.

Besides the rarity of axillary nodal metastases, the other argument against radical surgery is that the truly malignant variant of cystosarcoma phyllodes causes death in almost all patients, regardless of treatment. As Haagensen[12] stated "it is not reasonable to perform radical surgery for disease that is incurable." In the present series of patients, all three malignant tumors were treated by local excision and no recurrences as yet occurred, but neither patient had evidence of systemic metastases.

Finally it has been argued that radical surgery is unnecessary because the biologic behavior of the tumor is unpredictable. Reexcision of recurrent histologically malignant tumors has proven to be adequate therapy. Contarini et al[4] concluded that more radical procedures than wide local excision are not justified because cystosarcoma phyllodes behaves more like a soft tissue sarcoma than a breast gland tumor.

Conclusions

1) Cystosarcoma phyllodes is a rare breast tumor, and our understanding of the disease in incomplete.
2) Malignant behavior of cystosarcoma phyllodes is difficult to predict. The histologic criteria used to classify tumors as malignant are frequent mitotic figures, atypicality of the stromal cells, stromal overgrowth, and tumor necrosis.

3) Based on the present series and review of the literature, wide local excision of the tumor including a surrounding margin of normal breast tissue appears to be adequate therapy for both benign and malignant disease.

4) Close follow-up of all patients, with local reexcision for recurrent breast masses, is necessary because local recurrence is common.

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Important Advances in Clinical Medicine

Anesthesiology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in anesthesiology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in anesthesiology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Anesthesiology of the California Medical Association, and the summaries were prepared under its direction.

Glucose Administration During Neurosurgical Procedures

THE routine use of glucose-containing solutions during surgical procedures has recently been questioned, and the potential risks and benefits of glucose administration have been reexamined. Intraoperative hypoglycemia is unlikely to occur in the majority of adult patients who receive glucose-free intravenous solutions during a major operation. Conversely, even moderate rates of glucose infusion may magnify the tendency for blood glucose levels to increase intraoperatively during major surgical procedures. Considerable evidence that hyperglycemia augments neurologic damage caused by global cerebral ischemia has led to the recommendation that intraoperative glucose administration be avoided in patients at risk for cerebral ischemia.

Rhesus monkeys receiving a glucose load before cardiac arrest were noted to have increased neurologic damage compared with food-deprived monkeys. Subsequent studies in a variety of animal species, including primates, have confirmed the deleterious effect of hyperglycemia on the neurologic outcome in models of global ischemia. This effect occurs in animals with relatively modest elevations of blood glucose concentration.

Clinical studies have shown an association between elevated blood glucose concentration and poor neurologic outcome following cardiac arrest in humans. In these patients, however, the hyperglycemia seen with more severe injury may be the result of the neurohumoral response to stress rather than the cause of the injury. Although a correlation between hyperglycemia and an exacerbation of brain damage due to global ischemia has not been confirmed in humans, documentation in a variety of animal models suggests the effect is unlikely to be species-specific.

The mechanism whereby glucose administration exacerbates ischemic neuronal injury is not known. An accepted hypothesis is that the effect is related to increased lactic acid accumulation due to anaerobic glucose metabolism when the brain glucose level is elevated during an ischemic insult.

The influence of glucose administration on focal cerebral ischemia is considerably more controversial. Factors that may alter the effect of blood glucose concentration on focal ischemic injury include the site of the injury, the existence of collateral circulation, and whether the ischemic injury is transient or permanent. A correlation between increased glucose concentration and poor neurologic outcome has been shown in a number of clinical studies of patients with acute cerebral infarction, but other studies have failed to corroborate this association. Hyperglycemia has been shown to exacerbate neurologic damage in some animal models of focal cerebral ischemia. In other animal models, hyperglycemia appears actually to exert a protective effect.

In summary, although the adverse effect of hyperglycemia on neurologic damage associated with global cerebral ischemia has been fairly conclusively demonstrated, the influence of hyperglycemia on focal ischemia is not

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well defined. Patients undergoing neurosurgical procedures are frequently at risk for focal ischemia. Further investigation is needed to clarify this potentially important issue in the care of neurosurgical patients.

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Developing Standards for Patient Monitoring During Anesthesia

AN analysis of anesthetic cases resulting in serious morbidity or death has revealed that many could be prevented with better monitoring. During the 1980s at Harvard Medical School, the anesthesia department in conjunction with their risk management team developed specific monitoring standards to be followed in that institution. These standards, published in 1986 in *The Journal of the American Medical Association,* became the first nationally published standards governing minute-by-minute anesthesia care. The American Society of Anesthesiologists (ASA) adopted a similar intraoperative monitoring standard in 1986.

These initial standards established a maximum time interval of 5 minutes between measuring the blood pressure and the heart rate. Continuous monitoring of the heart by electrocardiogram and of the amount of inspired oxygen by an oxygen analyzer are required. If a ventilator is used, a disconnect alarm must be functional. Auscultation of the heart and breath sounds or other continuous mechanical monitoring of these variables was part of the standards. Also required are the ready availability of equipment to measure the patient's temperature and the continuous presence with the patient of the anesthesia personnel. Exceptions to some of these quidelines are infrequently allowed.

In 1989 the ASA amended these standards to require quantitative methods of assessing blood oxygenation—that is, pulse oximetry. Strong encouragement to include continuous end-tidal carbon dioxide measurement as a standard should lead to its adoption soon. Certainly other monitoring capabilities will be included as technology makes them available.

During the past three years similar standards for all anesthetics have been adopted in New Jersey, New York, and Massachusetts, and many other states are currently contemplating their own standards. The ASA has attempted to work closely with the legislatures to make this legislation acceptable on a practical and medicolegal basis.

Have these standards improved patient safety? Malpractice carriers seem to think they are beneficial because several gave immediate discounts to anesthesiologists adopting these standards. In addition, anesthesiology may be the only medical specialty to see its malpractice rates drop during the past several years as insurance companies downgraded its risk category. During this time, critics point out, newer anesthesia equipment has been introduced, better-trained anesthesia personnel have entered practice, and safer drugs have been developed. What effect each of these factors has had on patient safety is not certain, but preliminary data through 1988 since Harvard adopted its monitoring standards have shown a trend toward a 70% reduction in preventable anesthetic accidents. Anesthesia monitoring standards are clearly here to stay, and specific practice standards will continue to be added in the future.

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Noninvasive Cardiac Output Measurement

THERMODILUTION cardiac output is often measured to evaluate heart function in critically ill patients or patients undergoing a major operation. Pulmonary artery catheterization, which is required to measure the thermodilution cardiac output, has potentially serious complications, such as malignant arrhythmia, pneumothorax, and even death. It has recently been proposed that these risks do not outweigh the benefits of pulmonary catheterization. Thus, noninvasive cardiac output measurement techniques become attractive if they can provide some benefits of pulmonary artery catheterization—that is, cardiac output measurement—with reduced patient risk.

Two types of noninvasive cardiac output measurement are currently available: thoracic bioimpedance and Doppler ultrasonography. In thoracic bioimpedance, electrodes are placed on the patient's neck and thorax, and a high-frequency microcurrent is injected into one set of electrodes, with differences in the current detected by another electrode set. Pulsatile changes in the thoracic electrical resistance (impedance) are attributed to cardiac systole and used to calculate the stroke volume. Doppler ultrasonography measures cardiac output by measuring aortic blood velocity. The integral of the aortic blood velocity during systole, when multiplied by the cross-sectional area of the aorta, yields the stroke volume. Ascending aortic blood velocity can be measured at the suprasternal notch and inside the trachea (at the tip of an endotracheal tube). Descending aortic blood velocity can be measured from the esophagus (at the tip of an esophageal probe).

Each noninvasive method has different advantages and disadvantages. Bioimpedance electrodes are easily applied and can provide continuous estimates of cardiac output but are sensitive to electrical interference. Doppler techniques generally measure the aortic blood velocity well, but their absolute accuracy depends on knowing the aortic cross-sectional area. Using a cross-sectional aortic area derived from a nomogram decreases the accuracy, and measuring the aortic diameter with other techniques such as two-dimensional or M-mode echocardiography requires highly skilled examiners. Further, the cross-sectional area of the aorta may not be constant.

Thoracic bioimpedance, esophageal Doppler, and transtracheal Doppler can measure the cardiac output continuously, but suprasternal Doppler can measure cardiac output intermittently. Both techniques have variable agreement with thermodilution. Some of the difference between thermodilution and the noninvasive methods may be due to a variability in the thermodilution measurement itself rather than the noninvasive.

In their current form, neither bioimpedance nor Doppler ultrasonography can totally replace thermodilution cardiac output measurement. It is hoped they will either prove to be useful in following trend changes in cardiac output or that their technology will be further improved until they can be substituted for thermodilution cardiac output measurements.

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Transdermal-Mucosal Sedative and Analgesic Delivery

ALTHOUGH the skin and mucosal membranes of the mouth and nose have long been used for drug delivery, until recently these sites had been overlooked as locations for administering analgesic and sedative-hypnotic drugs. In the past few years, however, research and clinical testing of nonparenteral, noninvasive routes of anesthetic delivery have been active. New vehicles including skin patches, nasal sprays, buccal tablets, and lozenges on a handle have been developed to enable the safe, simple, and efficacious delivery of transdermal and transmucosal anesthetics. Certain patient groups such as children will benefit from these new technologies because an intravenous or intramuscular injection will no longer be necessary for the delivery of potent anesthetics and analgesics. Patient compliance may be greatly improved—compared with that with orally ingested pills—sustained-release systems using transdermal and transmucosal delivery permit less-often dosing schedules. The clinical application of transdermal and transmucosal anesthetic and analgesic systems includes preoperative sedation and lessening of anxiety, acute postoperative analgesia, and the treatment of chronic pain.

The preoperative administration of sufentanil citrate or midazolam hydrochloride nasal aerosols to children is a simple, relatively pain-free method of reducing the stress and anxiety of impending anesthesia and surgery. Undiluted sufentanil can be administered in doses ranging from 1 to 2 µg per kg with a rapid (within 10 minutes) onset of sedation and willing parental separation. Midazolam is given in doses ranging from 0.1 to 0.3 mg per kg with similar effects. One disadvantage of this technique is that most children cry briefly from irritation of the nasal mucosa. Children receiving intranasal premedication (especially sufentanil) must be monitored closely because respiratory depression may occur.

Buprenorphine hydrochloride is a long-acting, highly potent, mixed-opioid agonist-antagonist that is well absorbed sublingually owing to its high lipophilicity. Unlike buccal or sublingual morphine sulfate, which has a bitter taste, sublingual buprenorphine is taken well by children. A single dose provides excellent, long-lasting (up to eight hours) postoperative analgesia with less drowsiness and sedation compared with comparable doses of intramuscular morphine or meperidine hydrochloride. Although Buprenex (injectable) has been approved by the Food and Drug Administration (FDA), sublingual buprenophine (tablet) has not been approved for clinical use in the United States. Several reports of long-lasting respiratory depression not easily reversed by administering naloxone hydrochloride may adversely affect regulatory approval.

Oral transmucosal fentanyl citrate is a fentanyl-impregnated sucrose-based lozenge that has a handle attached to it. As patients suck on the lozenge, fentanyl is released to the oral mucosa for absorption. The patient or clinician is able to regulate delivery by removing the lozenge when the desired clinical effect (sedation or analgesia) is reached. This novel delivery system has obvious appeal, especially to children, because it is easy to administer and pleasing to taste. While not currently approved by the FDA for routine clinical use, transmucosal fentanyl in doses ranging from 10 to 20 μg per kg has been tested in clinical trials for pediatric premedication, postoperative analgesia, sedation for emergency department procedures, and the treatment of breakthrough cancer pain.

Even though the skin is difficult to penetrate, a fentanyl controlled-release skin patch (TTS-fentanyl) has been developed that allows systemic absorption. The patch releases fentanyl at a rate of 100 μg per hour and provides steady-state plasma concentrations for as long as the patch is in place. After the patch is removed, plasma fentanyl concentrations decrease slowly (elimination half-life is 18 to 21 hours), reflecting continued absorption from a reservoir in the stratum corneum. Thus, a rapid termination of drug action would be difficult if the patch had to be removed for opioid-related side effects. Nonetheless, TTS-fentanyl affords excellent, long-lasting postoperative analgesia without the discomfort and erratic absorption that occurs with intramuscular injections. While not currently on the market, TTS-fentanyl is undergoing regulatory approval by the FDA.

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Pain Management in Children

A wealth of information about the mechanisms of pain and pain management in children has proliferated in the professional literature. Still, children remain an underprivileged class in terms of access to therapeutic interventions for pain because many physicians do not fully appreciated the existence or perceptions of pain in children or the rational risks of pharmacologic intervention. Perceptions and tolerance of pain are highly subjective and extremely variable in the adult population. In children, the problem of assessing pain becomes much more problematic. Pain perception is usually associated with strong emotions that are assumed by many not to be present in young children, especially neonates. Many sources of bias and misinformation exist that often obviate appropriate pain therapy for children. These include assumptions that infants have no memory, so they will not be affected by the pain experience; children lack a well-developed nervous system, which prevents them from experiencing pain; and the adverse effects of analgesics and anesthetics are already considerable and are only compounded when used in combination with additional postoperative pain therapies. A review of biochemical, physiologic, and histologic evidence has largely dispelled these beliefs.

To respond appropriately to a child's pain, a physician must be able to recognize the existence of the pain. The most obvious clues are changes in behavioral responses such as fluctuation in heart rate, changes in respiration, palmar sweating, and increases in intracranial pressure that may be observed with the performance of invasive procedures in neonates. Additional diagnostic information can be obtained from a working knowledge of a child's various cognitive and maturational levels or from pain assessment tools involving subjective, behavioral, or physiologic measures. With preverbal children, physiologic and behavioral measures are most often employed. Direct reporting measures, such as visual analogue, face, and color scales to represent levels of pain, have also been effective in characterizations of pain in verbal children.

Although the intramuscular use of opiates remains the most commonly accepted method of pain relief in the pediatric population, regional neural blockade is perhaps another effective means of providing postoperative pain relief in children. Appropriate patients, drugs, and types of regional blocks must be selected carefully. The duration of the blockade can be extended with the use of indwelling catheters placed in the epidural, caudal, or intrathecal space or adjacent to various neural plexuses such as the brachial plexus. A catheter can be inserted safely into the caudal space and threaded to the midthoracic level to provide profound pain relief from a thoracotomy incision. When given in conjunction with opioids, local anesthetics can provide a longer duration of pain relief. Epidural bupivacaine hydrochloride, 0.1% to 0.125%, plus fentanyl, 2 μg per ml, infused at 0.2 to 0.4 ml per kg of body weight per hour provides excellent postoperative pain relief. Examples of the use of regional anesthesia include patients with cystic fibrosis who have suffered rib fractures. When treated with continuous epidural local anesthetics, they are more comfortable and demonstrate improvement in their respiratory status. Epidural blockade has also been used to improve regional blood flow to the extremities in patients with purpura fulminans due to meningococcemia and in patients with Kawasaki's disease. A number of regional anesthetic techniques commonly used in children have been recently reviewed.

The use of patient-controlled anesthesia (PCA) devices in children has gained broader acceptance in the anesthesia community. The efficacy of these devices stems from their ability to maintain a constant minimum blood concentration of analgesic. This is in contrast to the erratic levels that typically occur with the use of intramuscular analgesia. The use of PCA devices obviates the need for intramuscular injections, a source of anxiety and discomfort for children. The PCA devices have been especially useful in patients with sickle cell disorders and have been used for children as young as 5 years. Patients must be carefully screened and instructed before PCA therapy. A morphine sulfate concentration of 1 mg per ml is used at UCLA Medical Center. Bolus doses of 0.015 mg per kg can be self-administered at a predetermined interval, typically 10 minutes. The maximum 4-hour dose that patients can give themselves is usually set a 0.25 mg per kg. The bolus dose, basal infusion rate (constant background infusion rate), and lockout period (mandatory time interval between doses) can be independently varied to each patient.

Although children in pain are also seen in emergency departments, pain management is often overlooked there. A wide variety of agents including nitrous oxide in a 50/50 mixture with oxygen, midazolam given rectally or intranasally (0.3 mg per kg), and ketamine hydrochloride (0.5 mg per kg) given intravenously will safely alleviate pain and anxiety.

Prophylactic and adjunctive nonsteroidal anti-inflammatory therapy has long been advocated for the treatment of cancer and joint pain. An intravenous preparation of indomethacin, a nonsteroidal anti-inflammatory agent, has been efficacious in treating postoperative pain in children.

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Intravenous Propofol Anesthesia

THE development of the drug propofol, which is characterized by a rapid onset and termination of action, and advances in the design and capabilities of infusion pumps, have led to a renewed interest in the use of intravenous techniques for the maintenance of anesthesia. It is now possible to titrate an intravenous infusion of propofol in response to surgical stimuli in the manner in which a vaporizer of a volatile agent is currently used.

After an induction dose is administered to fill the initial volume of distribution, an infusion rate that matches the clearance of the drug will maintain a constant blood level of propofol and anesthesia. As the kinetics of propofol are linear within the range used for continuous infusions, higher or lower concentrations should be easily achieved by changing the infusion rate. These predictions have been borne out in clinical practice, and several infusion regimens have been described.

Comparative studies have found a propoful infusion to be a suitable alternative to induction with thiopental sodium and maintenance with halothane, isoflurane, or enflurane. It is associated with a rapid recovery and a low incidence of nausea and vomiting. When combined with an analgesic and a muscle relaxant, it is suitable for total intravenous anesthesia. By itself, propofol may be used in subanesthetic doses to provide sedation for patients undergoing a surgical procedure under regional anesthesia or for patient in intensive care units. With a reduction of the infusion rate, it may be used safely in the elderly, and prolonged use does not cause adrenocortical suppression.

Side effects that are seen when the agent is used for induction are less apparent than when used for continuous infusion, namely, dose-dependent cardiovascular depression. Metabolism and excretion are not affected by moderate hepatic or renal impairment.

Recent advances in infusion pump technology have greatly simplified and added to the safety of continuous infusion techniques. Small battery-operated pumps can be programmed for an individual drug and patient weight to display the infusion rate in milligrams per kilogram per hour rather than milliliters per hour. This avoids anesthetist error in complex calculation of infusion rates, thereby increasing safety. These pumps have proved to be simple and useful for propofol infusions, where the basal rate can be adjusted to take into account the age of the patient, concurrent drug therapy, and preexisting disease states.

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Black-White Disparities in Health Care

AMA COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

Persistent, and sometimes substantial, differences continue to exist in the quality of health among Americans. Blacks have higher infant mortality rates and shorter life expectancies than whites. Underlying the disparities in the quality of health among Americans are differences in both need and access. Moreover, recent studies have suggested that even when blacks gain access to the health care system, they are less likely than whites to receive certain surgical or other therapies. These studies have examined treatments in several areas, including cardiology and cardiac surgery, kidney transplantation, general internal medicine, and obstetrics. Whether the disparities in treatment decisions are caused by differences in income and education, sociocultural factors, or failures by the medical profession, they are unjustifiable and must be eliminated. In this report, the Council on Ethical and Judicial Affairs of the American Medical Association emphasizes the need for (1) greater access to necessary health care or black Americans, (2) greater awareness among physicians of existing and potential disparities in treatment, and (3) the continued development of practice parameters, including criteria that would preclude or diminish racial disparities in health care decisions.

THERE are persistent, and sometimes substantial, differences in the quality of health among Americans. Despite improvements in health care for black Americans since the 1960s, blacks have twice the infant mortality rate of whites and a life expectancy of white Americans *(New York Times*. March 16, 1989:B15). Black men younger than 45 years have a 45% higher rate of lung cancer and 10 times the likelihood of dying from hypertension than white men younger than 45 years *(New York Times*. July 17, 1989:A11). Underlying the racial disparities in the quality of health among Americans are differences in both need and access. Blacks are more likely to require health care but are less likely to receive health care services.

The disparity between blacks and whites in access to health care reflects the continuing disparities in their income, education, and other characteristics that correlate with the receipt of any complex and expensive service. But medical care is a unique and essential service and substantial disparities cannot be tolerated. Equal access to basic medical care by all Americans is a longstanding policy of this country and the American Medical Association.

Moreover, recent studies have suggested that even when blacks gain access to the health care system, they are less likely than whites to receive certain surgical or other therapies. These studies vary in their purpose, depth, and validity, but they cannot be ignored. This report reviews the recent studies and discusses their significance.

Many of the disparities that exist for black patients also exist for other racial minorities, although there has not been the same degree of documentation in such cases. The concerns expressed in this report apply equally to other racial minorities.

Evidence of Disparities in Medical Treatment

Recent studies have suggested that the use of specific medical treatments differs between black and white patients. These studies have examined treatments in several areas, including cardiology and cardiac surgery, kidney transplantation, general internal medicine, and obstetrics.

In a national survey of patients who were discharged from hospitals with a diagnosis of anterior myocardial infarction, black men had a rate of anterior myocardial infarction that was three fourths of the rate for white men. However, the black men were only half as likely to undergo angiography and one third as likely to undergo bypass surgery as the white men.[1] On the other hand, mortality rates suggested that the severity of illness was comparable between blacks and whites at the time of admission. Nineteen percent of the whites and 18% of the blacks died while hospitalized for their anterior myocardial infarction. Long-term survival rates were not measured.

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Another study reviewed data on all patients discharged from Massachusetts hospitals in 1985 with a preliminary diagnosis of circulatory system disease or chest pain.[2] While blacks and whites had similar rates of hospitalization, whites were one third more likely to undergo coronary angiography and more than twice as likely to be treated with bypass surgery or angioplasty. The racial disparities persisted even after differences in income and the severity of disease were taken into account. In a study of all patients who underwent coronary angiography between 1970 and 1978 at a major tertiary care center, whites were two to three times more likely to undergo bypass surgery than blacks who had similar clinical characteristics.[3] Similarly, in a study of data from the Coronary Artery Surgery Study, which enrolled patients in 1974 through 1979 from 15 geographically diverse academic institutions, a large differential between blacks and whites in the rate of bypass surgery could not be explained by differences in clinical or angiographic characteristics.[4] In that study, surgery was recommended for whites more often than for blacks and, among those for whom surgery was recommended, whites were more likely to have the surgery performed. In addition, among those for whom medical treatment was recommended, whites were more likely than blacks to undergo bypass surgery.

Racial status has also been found to correlate with the likelihood that a patient with kidney disease will receive long-term hemodialysis or a kidney transplant. Racial disparities in access to long-term hemodialysis are on the order of 5% to 15%; the most favored person is the white man aged 25 through 44 years.[5]

Several studies have documented racial disparities among patients who undergo kidney transplantation. In one study, the researchers reviewed all patients who received long-term dialysis in the United States in 1983 and all patients who recieved long-term dialysis in the upper Midwest Between 1979 and 1985. Nonwhite dialysis recipients were two thirds as likely as white patients to receive a kidney transplant.[6]

A review of patients with end-stage renal disease who were covered by Medicare benefits form 1977 through 1985 revealed that blacks accounted for 33% of patients with end-stage renal disease, but only 21% of patients who received kidney transplants.[7] In a national survey of nearly 15,000 patients who began treatment for end-stage renal disease between 1981 and 1985 who were therefore covered by Medicare benefits, researchers found that the likelihood of receiving a kidney transplant correlated with race and income and that the effects of race and income were independent of each other.[8] Patients who were treated at institutions that served a predominantly white population and that were located in high-income areas were almost twice as likely to receive a transplant as patients who were treated at institutions that served a predominantly black population and that were located in low-income areas.

While the patients in these studies were covered by Medicare, differences in income were still important. Until 1987, Medicare did not pay any of the bills for outpatient drugs, which, in the case of the immunosuppressive drug cyclosporine, could cost as much as $5000 annually. In addition, for patients who do not live near a transplant center, transportation costs may be substantial.[8]

The evidence of racial disparities in treatment decisions also appears in general internal medicine. A study of treatment for patients hospitalized because of pneumonia found that the patient's race correlated with the intensity of care provided.[9] The researchers reviewed all patients hospitalized with a primary diagnosis of pneumonia in 17 hospitals between 1970 and 1973. The hospitals were selected in a manner designed to ensure that they varied in size, teaching status, and expenditures per patient. The study showed that, after controlling for differences in clinical characteristics and income, blacks were less likely to receive medical services, particularly intensive care.[9]

In a review of 65,000 deliveries in four New York, NY, hospitals during a 5-year period, researchers found that private patients were more likely than clinic patients to have a cesarean section, even though the private patients were less likely to have medical problems or to be delivered of low-birth-weight babies.[10] The disparity in cesarean section rate between private and clinic patients carried over to the subgroup of patients who were considered to be at low risk for a cesarean delivery. While 47% of the clinic patients were black, 22% of the private patients were black. Thus, blacks were probably less likely than whites to receive cesarean sections even when clinically comparable.

Racial disparities in treatment decisions have been documented previously. In a study of hospital admissions from the emergency department of a major tertiary care hospital during 1968, researchers found that blacks were more likely to be classified as ward patients and whites to be classified as private patients, even when there was a comparable ability to pay for care.[11] In addition, ward patients were less frequently admitted to the hospital even when clincial characteristics were similar. Studies from the psychiatric literature in the 1960s indicated that black patients were less often accepted for psychotherapy, more often assigned to inexperienced therapists, and seen for shorter periods and with less intensity.[12]

The racial disparities in treatment decisions are consistent with studies of patient perceptions. A national telephone survey conducted in 1986 found that blacks were more likely than whites to report that their physician did not inquire sufficiently about their pain, did not tell them how long it would take for prescribed medicine to work, did not explain the seriousness of their illness or injury, and did not discuss test and examination findings.[13] In addition, blacks were less likely than whites to be satisfied with the care provided during their most recent hospitalization or ambulatory care visit. Similar results were found in a survey of patients with hypertension in Edgecombe County, North Carolina.[14] Compared with white patients, the black patients reported more general difficulties getting into the health care system and greater dissatisfaction with medical care services.

Reasons for Racial Disparities

It is difficult to draw firm conclusions from these studies regarding the role of race in decisions to treat patients. With regard to bypass surgery, for example, while the studies tried to control for incidence and severity of disease, they generally did not control for other relevant variables they may account for the differences between blacks and whites. In the Massachusetts study, where the data were adjusted for differences in age, gender, severity of disease, income, and type of insurance, and racial disparities in the frequency of bypass surgery were still found, the researchers did not have actual income data but used the patient's residence as a proxy for income.[2] That is, they assumed that the patient's income was the average household income for people living in the patient's ZIP code. With more precise data, there might be a decrease in the extent of the racial disparities.

Some of the disparity in kidney transplantation rates may be explained by medical or biologic differences. For example, most of the kidneys donated for transplantation come from whites and intraracial antigen matching is often more favorable than interracial matching.[8] However, it is unlikely that medical differences account for all of the disparities. Whites not only are more likely to receive transplants, but they appear disproportionately on waiting lists for transplants.[8]

Income differences are probably the most important explanation for the disparities. Race and income are highly correlated and patients with higher incomes are better able to bear the direct and indirect costs of expensive medical procedures.

Some medical experts have also suggested that physicians are more likely to treat aggressively patients who are wealthier, more productively employed, and more assertive *(New York Times*, January 24, 1989;C1).[15] Such patients might be viewed as more likely to respond successfully to therapy. It has also been suggested that they might be viewed as more valuable to society.[8] In addition, there is a natural tendency to respond to those who are persistent in their requests for services.

Other factors, of course, such as education and the skills that come from it, inevitably restrict the ability of some blacks to gain access to and to negotiate effectively for the best medical treatment available. Commentators have also speculated that blacks and whites may differ in terms of their treatment preferences, although such a difference has not been documented.

Disparities in treatment decisions may reflect the existence of subconscious bias. This is a serious and troubling problem. Despite the progress of the past 25 years, racial prejudice has not been entirely eliminated in this country. The health care system, like all other elements of society, has not fully eradicated this prejudice.

Significance and Response

Whether the racial disparities in treatment decisions are caused by differences in income and education, sociocultural factors, or failures by the medical profession, they are unjustifiable and must be eliminated. Not only do the disparities violate fundamental principles of fairness, justice, and medical ethics, they may be part of the reason for the poorer quality of health of blacks in the United States.

The Council recognizes the complexity of the problem and the efforts within and outside organized medicine to address it. The Council emphasizes three approaches that it believes should be given high priority:

1. Greater access: The studies discussed in this report underscore the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. The American Medical Association has recommended several measures to increase access to health care for the uninsured.[16,17] These include *(a)* a requirement that employers provide health insurance for all full-time employees and *(b)* for individuals who are not employed on a full-time basis, (1) reform of the Medicaid program to ensure adequate coverage for all Americans with incomes below the federal poverty level, (2) establishment of state risk pools to provide health insurance through the private sector at group rates for individuals earning between 100% and 200% of the poverty level of income, with provision of publicly funded vouchers on a sliding scale to those earning between 100% and 150% of the poverty level of income, and (3) publicly funded, state indigent-care funds to finance health care for patients who remain without adequate insurance coverage.

2. Greater awareness: Because racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race, physicians should examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place as part of the medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.

Awareness of and responsiveness to the sociocultural factors underlying the disparities in treatment can also be enhanced by increasing the numbers of black Americans in medical school faculties and student bodies. The American Medical Association has recommended a number of measures to increase minority representation in medicine: (1) expansion of recruitment efforts, including special premedical and precollegiate programs for minority students, (2) greater government financial aid to those in need at both the collegiate and medical school levels, (3) affirmative action in medical school admission and faculty-hiring decisions, (4) more supportive academic programs for minority students (through tutorials and other academic assistance, decelerated schedules as required, and early orientations), and (5) competent and sensitive student counseling and advisory services.[18,19] The American Medical Association is currently developing new strategies to increase the recruitment and retention of minority medical students and faculty members.[20]

3. Practice parameters: The racial disparities in treatment decisions indicate that inappropriate considerations may enter the decision-making process. The efforts of the specialty societies, with the coordination and assistance of the American Medical Association, to develop practice parameters should include criteria that would preclude or diminish racial disparities.

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A Privilege and an Honor

HENRY SCHNEIDERMAN, M.D.

JACOB Shulewitz had reached the age of 91-and-a-half years when he became my patient. (Note that all names have been changed to protect privacy.) The referral came from his grand-niece Barbara Weiss, a medical student for whom I served as clinical advisor; the family felt he needed a more attentive general internist, what with his ten-item problem list and his periodically active diverticular disease of the colon. We had a first long symptom-independent visit to establish a baseline. During the interview I discovered that this pillar of his synagogue was not at all the forbidding, remote, and exclusionary type that fit my prejudice about the deeply orthodox. Rather, he proved to be down-to-earth, unassuming, and respectful to a degree that was both touching and ludicrous especially because he was 58 years my elder. He was spontaneous in his reactions and initiatives, gently humorous, and very individualized in his approach to each person he met. He was still employed part-time as a kosher butcher and had lived alone since the death of his wife. Everybody in his loving extended family called him Uncle Jack; a cluster of devoted fellow congregants referred to him as Jack. His nurse, the resident, and I all voiced hopes that if we were to live so long, we too might retain command of faculties and display nine decades of character growth as he did.

I saw him again at Barbara's graduation, where he was at once proud and self-effacing. A few months later I hospitalized him overnight for acute diarrhea that in retrospect had no ominous underlying cause. I found him reading Hebrew prayers in the chair beside his hospital bed the next morning. He wore the fringed prayer shawl on his shoulders and the yarmulke that would leave his head only in the operating room. Medicare denied payment. I was furious and ranted, "God damn it, the next time I have a 92-year-old with heart disease, blood-flecked diarrhea, and a real danger of dehydration, I'll bring him in the hospital, too, no matter what these bastards say!" It's only now that I recognize how the blasphemy would have offended him had it been spoken in his presence.

After Joseph was born, Mr. Shulewitz never failed to ask, "And how is the little man?" when he came to the office. He always studied the latest photograph with attention and pleasure. "What a serene old age," I thought. Wrong. *His* only son, aged 60 or so, was admitted to a hospital in another city for dangerous but necessary surgery and developed calamitous neurologic complications that, among other things, left him permanently dependent on a respirator. Uncle Jack's friends and family disagreed strongly on whether he could be told. Eventually he was, and he went to see his son, and survived the visit, and survived the son's death a little after. With Joseph in mind, I thought, "This was the very worst event that could ever befall him, even beyond his wife's death." He didn't want to talk about it much, and I was not going to push him, certainly not now.

Intestinal bleeding remained a vexing problem. One day, after I had wiped him at the conclusion of a rectal examination, and apologized for the indignity of it all, he said, "You're the most gracious doctor I ever met." Ultimately we had to consider a colonoscopy, a procedure that always demands so much tolerance and strength from the patient. I will always be grateful to the gastroenterologist, who had come to know Mr. Shulewitz as a person, for three things: the respect shown to Mr. Shulewitz's individuality, the freedom from agism, and the judgment of this consultant, who was rigorous but not procedure-

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Although the content of this report is factual, some names and identifying data have been changed to protect privacy.

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happy: "He deserves a hard look. If there is cancer at the root of the seepage, he has the fortitude to withstand major, potentially curative surgery and its consequences. It could save his life." After two failed outpatient attempts, we had to admit him for the procedure. He had said, "I won't celebrate Rosh Hashanah or Yom Kippur in the hospital," so we finessed him in and quickly got him out between the two holidays. The study was successful and negative. Medicare denied payment for the two-day stay and said, "Study could have been completed as an outpatient." My response was, "Thank you for having such flexibility about the diversity of human needs."

After this we transfused Mr. Shulewitz empirically every few months, replacing the red cells he had leaked we knew not where into his gut. We would make a partial (day) admission of the transfusion. The nurses got to know him and were charmed by him; Jeanette in particular would ask to take care of him when he was coming in, and would inquire about him when he was not. Once the intern ordered a diet without specifying that it be kosher; Uncle Jack told the nurse, "Don't worry," and would have spent the day fasting without a word of complaint if she hadn't intervened.

He finally had to stop working. I suspected that bereavement and life stress had produced some functional decline in his mental power. The housekeeper/friend who came in daily found that the stovetop burner had been left on one day, and that he was unaware of it. We had many conferences to try to keep things safe for him, and to spare her having to double her trips. His level of self-care and personal appearance declined, although he still cut a fine figure if his niece — Barbara's mother, Mrs. Weiss — or a friend assisted him. The disputes among concerned friends and family about maintaining his independence raged for months, and were complicated by his firm stance: "Any place I wind up must have a kosher kitchen."

Although I never called him Uncle Jack myself, I started to think of him by that name after the twentieth telephone call during which his niece referred to him that way. He never took me up on the offer that he use *my* first name. During one telephone conversation, Mr. Shulewitz, who had had very little formal education, complained to me about a would-be guardian, "He is trying to usurp my prerogative," and the analysis was utterly apt; that was Mr. Shulewitz's level of insight and articulation at the age of 93.

All parties agreed that he would react poorly to displacement into a nursing home, but a time came when our contortions failed and it had to be. He developed pneumonia soon afterward and was admitted into an acute hospital outside my care. Mrs. Weiss kept me posted; by this time Barbara was a fellow in Geriatric Medicine in another city, and we occasionally would talk about her great-uncle by telephone. A confusional state that began when Uncle Jack was infected was very slow to clear even after he improved, defervesced for good, and returned to the nursing home. He also had new problems with urinary incontinence and needed to have an indwelling urethral catheter. Needless to say, this was something he was ashamed of and detested. Because our own hospital's geriatric fellowship was up and running by this time, our fellow based at the nursing home would look in on him; the reports were not favorable. I would also get feedback and suggestions for management from some friends and members of his temple who clearly cared deeply for him; my dentist—who was my age and not his—was one of these.

Eventually I brought Mr. Shulewitz back to my hospital for study of his failure to thrive. There was still much light in his eyes, comprehension, wisdom, goodwill, and inquiry. He greeted me effusively. Mrs. Weiss reported that his language, spirits, and level of interaction jumped with the transfer. Clearly the environment in my hospital symbolized both familiarity and hope for a better quality of life. His deafness had worsened, and we struggled to get him a new and better hearing aid. I hoped that the communicative decline we perceived was related to sensory input loss, ie, not getting messages in because of poorer hearing. After shouting to no avail, I wrote complex notes to him. His comprehension and response in kind were reassuring. Our urologist agreed with Uncle Jack's wish to spend the remainder of his 95th year as he had all the others before it—without a catheter stuck up his penis.

He had to be readmitted electively for his prostate surgery. The cardiologists said that his aortic valve was now critically tight, and because of this they feared he would die on the operating table. The urologist said, "I'll keep the transurethral resection very brief, and the intraoperative irrigant fluid use to the minimum." Mr. Shulewitz left the hospital, continent, lucid, and pleased, three days after his operation.

After his discharge back to the nursing home I would ask the geriatrics fellow every so often how he was doing. The story was first one of dwindling faculties and general health, and then weight loss, unexplained fevers, and unconfirmable hints of infection somewhere in his system. After a month without news I suspected he must have died, but I didn't have the heart to confirm it. One of the fellows contacted me about another matter, and I asked. I heard that he was stable although diminished, and that he would inquire about me by name at every contact. I meant to go visit him, and for reasons that are not good enough I never did. Two weeks after the fellow's update, the dentist telephoned one morning to say Mr. Shulewitz had just died in his sleep; Barbara and her mother called with the same message later that day, and the fellow called a couple of days later.

Besides everything else, Mr. Shulewitz liberated me from an unjustified belief that the most religiously observant are unfriendly or clannish, a prejudicial generalization based on very limited life experience. Both substantively and symbolically he helped me recognize the depth of my interest in geriatrics; Barbara has said that he was a major role model and stimulus to her career choices in ways that are not diminished by his death and that are no less true because he never said, "Why don't you think about geriatrics?" I think he would be glad to know all this, but wouldn't make too much out of it.

I miss him. I feel he is with his forefathers and his son and with God, and at peace, notwithstanding the ambiguity of his religion about an afterlife. I can still see his face, one that Rembrandt would have painted, and his posture when I lie awake in the dark. It was an honor and a privilege for me as a professional person to work with him, to contribute what I could to the maintenance of the dear and sacred flesh that housed his beautiful spirit, and in a tiny way to give love to that spirit; as a human being I had undiluted pleasure and gratification in knowing him.

The Weisses approve the principle of this small memoir of him and say that he would have too.

CSMS HEALTH PROMOTION PAMPHLETS

The Connecticut State Medical Society Committee on Public Affairs recently approved eight new health promotion pamphlets that will be mailed to all members by early December. They are to be used for distribution in office waiting rooms. Members may order a limited number of additional pamphlet sets at no cost. These pamphlets will also be published in Spanish for those who will benefit from the translation.

Sets will also be distributed to libraries, school districts, legislators, business and industry, unions, news media and service agencies throughout the state. Watch for them.

Good Advice From Your Physicians

Title	**Content**
Living Smart	Health awareness of your lifestyle.
Smoking is Number One	Avoid the hazards of smoking.
Alcohol Abuse Kills	Effects of alcohol and alcoholism.
Eating to Live	Healthier eating habits.
Know Your Physician	What makes doctors tick.
The Physician-Patient Team	The key relationship for healing.
Health Care Costs and You	The good news and bad.
AIDS and Other STD's	Objective information and sound advice.

Please use these valuable tools in communication with your patients

Healthnet: Connecticut Consumer Health Information Network

ALBERTA L. RICHETELLE, M.P.H., M.S.L.S.

AUTHORITATIVE, up-to-date, and accessible information plays an important role in helping individuals make wise decisions about their health. A recognition of the importance of this kind of information was the impetus for the creation of Healthnet: Connecticut Consumer Health Information Network, a program of the library of the University of Connecticut Health Center in Farmington. The goal of Healthnet, which began in January 1985, is to maintain a network of public libraries, health agencies and associations, self-help groups, and the University of Connecticut Health Center library to encourage information sharing in order to provide Connecticut residents greater access to health information through their local public libraries. Further evidence for the need to develop such a program was provided by the results of a 1984 study conducted by the Connecticut State Library of the information needs of Connecticut residents. In a telephone survey of 500 households, health ranked third as an important information need with consumer issues and money matters ranking first and second.

Healthnet is based on the philosophy that informed persons make more responsible and knowledgeable decisions about their health and medical care. An important component of the program is to assist local public libraries to become access points for consumer health information. The local public library is a resource where a person can seek out information on a personal health concern as well as get an answer to a specific question and a referral for additional information to self-help groups, health agencies and associations, and other similar organizations. In this neutral setting, a person can obtain information on a wide range of health topics and be assisted by a professional librarian who acts impartially in identifying relevant resources. The University of Connecticut Health Center library serves as a backup for technical information that is not available locally.

Services provided by Healthnet to public libraries include:

1) training of public librarians in medical reference tools and techniques;
2) reference assistance to answer consumer health questions;
3) identification and evaluation of consumer health books, pamphlets, and audiovisuals;
4) preparation of subject bibliographies on consumer health topics;
5) assistance with developing presentations by local health professionals on current health issues;
6) publication of a newsletter to keep librarians informed of new information resources;
7) development of publicity programs and materials to promote public libraries as sources of consumer health information.

Training public librarians to answer medical questions is an important service provided by Healthnet. Workshops are held regularly and include a discussion of guidelines for providing medical information to consumers as well as a "hands-on" evaluation of titles included in a core list of reference books. Since 1985, 18 reference workshops have been presented and attended by approximately 300 librarians representing 100 public libraries throughout the state. The guidelines for answering medical questions cover information such as the appropriate way to handle requests for medical advice and opinion, how to answer questions related to prescription and nonprescription medications, what to do when a patron asks for assistance in making a diagnosis, providing information of a sensitive nature, and when and how to make referrals for additional information. Key features of each of the titles on a core list of consumer health reference books are discussed and examples are

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given of the kinds of medical questions each is capable of answering. An abbreviated list of titles discussed in these workshops is included at the end of this article.

During Healthnet's developmental stage a project was designed to upgrade the medical and health reference collections of public libraries. A core list of medical and health titles was developed and libraries were surveyed to determine what titles they owned. Purchases were then made for each of the 120 participating libraries to correct major deficiencies. All of the reference books purchased for this project are those that are discussed in the medical reference workshops. Examples of titles purchased for this project can be found in the select list of consumer health books that appears at the end of this article.

Special Healthnet projects have included the acquisitions of nutrition information materials for 140 public libraries throughout the state. This project, which was funded in part through a grant from the Connecticut State Library, was developed as a result of the concern by public librarians about the plethora of celebrity diet and nutrition books and a desire to balance library collections with current, authoritative nutrition information. Registered dietitians helped develop a core list of books on various nutrition topics such as cholesterol, weight loss, fiber, nutrition for children, food safety, and calcium and osteoporosis. Pamphlets were acquired from state and national organizations concerned with nutrition, including the American Dietetic Association, the New England Dairy Council, and the Connecticut Chapters of the American Heart Association and the Diabetes Association. The books and pamphlets, accompanied by bibliographies and publicity materials, were then distributed to each of the participating libraries which developed displays of the information during national nutrition month in March. Town newspapers were sent press releases to help advertise the availability of the nutrition information.

Another project involved the acquisition of a collection of videocassette programs on health issues for elderly persons. Representatives of health agencies and organizations serving the elderly were surveyed to determine general subject areas to be considered for purchase. Topics recommended included Alzheimer's disease, use of medications, exercise, sexuality, long-term care, nutrition, and handling grief and loss. Videocassette programs on these topics were then evaluated and a collection was purchased and made available through local public libraries. These videocassette programs have been popular with older individuals as well as community health professionals who have used the films with groups of older adults as springboards for discussion on specific topics.

Special projects of Healthnet have been developed in cooperation with the state's regional library cooperatives. Connecticut is divided into six regional Cooperating Library Service Units (CLSUs) which are private nonprofit organizations of multitype libraries. Each region has its own office and a staff that provides program assistance to improve library service through cooperation in sharing resources and developing new resources. The assistance provided by each of the CLSUs has made it possible for Healthnet services to reach public libraries in all parts of the state and to develop consumer health information programs that meet local community needs.

Informal surveys of health questions asked at public libraries show that about 30% are concerned with information on diseases and disorders and, more specifically, treatment options and prognoses. The second most frequently asked question (about 17%) concerns side effects of medications. Nutrition represents about 14% of reference questions, followed by questions concerning health care facilities (7%), and those concerning mental health (6%). Biographical information on health professionals, surgery, medical tests, environmental health, and general inquiries including more than one topic comprise the remaining questions. Cancer, diabetes, and heart disease represent a large number of the questions on treatment and prognosis of diseases. A little over 60% of the questions are posed by women. For the most part, most of these medical questions can be answered at the public library. If a question is complex or the library, because of its size, has limited resources, the question is referred to Healthnet. Over half of these referred questions concern specific diseases. Usually, they require very specific information such as the latest treatment for a particular disease or a description of a rare disease. Many of these referrals present unique problems because there is a general lack of appropriate information for the lay person on current treatments for specific diseases. By the time the question reaches Healthnet most of the standard references, many of them lay oriented, have been checked. These questions often come from patrons who are not satisfied with the very basic information supplied in the lay literature. Much time is spent on identifying information on the topic which is not only comprehensive and current, but which can be understood by someone with little or no medical training.

Information on medical tests and procedures and the identification of specialty clinics represent an additional 25% to 30% of the questions referred to Healthnet. It is interesting to note that there has been a definite increase in the number of reference referrals related to environmental health issues, in particular "sick building syndrome" and chemical pollutants.

Healthnet has used a variety of methods to encourage people to use their public libraries for their health information needs. Public service announcement have been produced and aired on radio stations throughout the state to call attention to the vast health information resources of local public libraries. Programs on popular health topics have been presented by health professionals in the community rooms of a number of libraries and month-long health information observances have been held in others. Posters have been prominently displayed and bookmarks and bibliographies highlighting different health information topics have been distributed to library patrons.

Healthnet has been successful in providing services to public libraries throughout the state to help meet the health information needs of their patrons. The greatest challenge for the future will be to encourage nonlibrary users to use the health information resources of their local public libraries. Creative ways need to be developed to bring the public library's resources to health programs in the community, such as neighborhood health clinics, community nutrition sites, and public health screening programs. In this way cooperative community efforts will be able to meet the growing diversity of demands by the public for health information.

A SELECT LIST OF CONSUMER HEALTH BOOKS AVAILABLE IN CONNECTICUT PUBLIC LIBRARIES

The following is a list of representative health and medical books purchased by Healthnet for public libraries in Connecticut. All titles may not be available at individual libraries.

Dictionaries, encyclopedias, directories

American Medical Association Encyclopedia of Medicine: An A-Z reference guide to over 5,000 medical terms, including symptoms, diseases, drugs, and treatments. Random House, 1989.

The Best in Medicine: Where to get the finest in health care for you and your family. By Herbert J. Dietrich and Virginia H. Biddle. Harmony Books, 1986.

Directory of Nursing Homes: A state by state listing of facilities and services. 2nd edition. Edited by Sam Mongeau. Oryx Press, 1988.

Dorland's Illustrated Medical Dictionary. 27th edition. Saunders, 1988.

Connecticut Directory of Self-Help/Mutual Support Groups. 1987-1988. New Haven. Connecticut Self-Help/Mutual Support Network. Free to public libraries upon request. Contact: Roxanna Simmons, 789-7645.

Health Care, U.S.A. By Jean Carper. Prentice Hall Press, 1987. Helps locate information on medical and health problems, including names, addresses, telephone numbers for doctors, hospitals, clinics, research centers, professional medical associations, self-help organizations, hospices, alternative treatments, government agencies, publications, hotlines.

Bibliographies

Consumer Health Information Sourcebook. 3rd edition. By Alan Rees and Catherine Hoffman. Oryx Press, 1989.

Contains reviews of the best consumer health books on a wide range of topics.

Learning AIDS: An information resources directory. 2nd ed. American Foundation for AIDS Research, distributed by R.R. Bowker, 1989.

An annotated, evaluative listing of AIDS educational materials.

Anatomy

The Johns Hopkins Atlas of Human and Functional Anatomy. 3rd ed. Revised and updated. Johns Hopkins Press, 1986.

Diseases, diagnosis, treatment

American Cancer Society Cancer Book: Prevention, detection, diagnosis, treatment, rehabilitation, cure. Edited by Arthur Holleb. Doubleday, 1986.

The American Medical Association Family Medical Guide. Revised and updated. Edited by Jeffrey R. Kunz. Random House, 1987.

Current Medical Diagnosis and Treatment. 27th ed. Edited by Marcus Krupp, et al. Lange, 1990. (published annually)

Merck Manual of Diagnosis and Therapy. 15th edition. Ed. By Robert Berklow. Merck, Sharpe & Dohme Research Laboratories, 1987.

Patients' Guide to Medical Tests. 3rd ed. revised and expanded. Cathey Pinckney and Edward Pinckney. Facts on File, 1987.

Professional Guide to Diseases: an up-to-date encyclopedia of illnesses, disorders, injuries and their treatments. 2nd edition. Ed. by Helen Hamilton and Barbara McVan. Springhouse, 1986.

Nutrition and diet

Food for Health. By M. E. Ensminger. Pegus Press, 1986. Information on all aspects of nutrition including descriptions of various foods, nutritional requirements, and nutritional diseases.

Food Values of Portions Commonly Used (Bowes and Church's) 15th ed. By Jean A.T. Pennington and Helen Nicols Church. Harper & Row, 1985.

Prescription and nonprescription drugs

Handbook of Non-prescription Drugs. 8th ed. American Pharmaceutical Association., The National Professional Society of Pharmacists, 1986.

USPDI: United States Pharmacopeia Dispensing Information. U.S. Pharmacopeia Convention, annual. Vol. 1 - Drug Information for the Health Care Provider; Vol 2 - Advice for the Patient.

Adenosine

ELEANOR A. O'RANGERS, PHARM.D.

Introduction

ADENOSINE is a purine nucleoside involved in numerous biochemical pathways in the human body. When released into extracellular fluid, it exerts various pharmacologic actions.[1,2] Discovery of its unique antiarrhythmic properties has led to the recent FDA approval of exogenous adenosine (Adenocard®, Lyphomed, Inc.) for the treatment of paroxysmal supraventricular tachycardia (PSVT).[3]

Pharmacology

Adenosine exerts transient negative chronotropic and dromotropic (affecting conduction) effects on both cardiac pacemaker tissue and atrioventricular (AV) conduction,[1-4] which results in the reduction of sinoatrial (SA) nodal discharge and the prolongation of atrial to ventricular conduction time. It has no effect on ventricular or His bundle conduction.[1,4-6] In patients with supraventricular tachycardias (SVT) involving the AV node—specifically atrioventricular reciprocating tachycardia and atrioventricular nodal reentry tachycardia—adenosine blocks both antegrade (atrial to ventricular) conduction and retrograde (ventricular to atrial) conduction.[4-6]

The precise mechanism of adenosine's antiarrhythmic activity is still unknown, but it is believed to be receptor-mediated.[2] Adenosine may block cellular calcium influx and enhance potassium conductance in cardiac myocytes. These properties can alter spontaneous depolarization in slow-channel dependent tissue (such as the SA and AV nodes) and in atrial tissue.[1] Decreased catecholamine triggered automaticity may also be involved in adenosine's antiarrhythmic efficacy.[2]

Pharmacokinetics

Because adenosine is not absorbed when given orally, intravenous administration is necessary for effect. Once injected, adenosine is rapidly taken up by erythrocytes and vascular endothelium. It is then metabolized by adenosine deaminase to inosine, and ultimately to uric acid, which is eliminated by the kidneys. Adenosine is also converted to cyclic adenosine monophosphate (cAMP) and other adenine nucleotides by adenosine kinase. The half-line of adenosine in the circulation is less than 10 seconds. Because of its rapid metabolism, much of adenosine's pharmacokinetics are poorly defined. However, because of its direct activity and intravascular metabolism, hepatic and renal impairment should have no effect on the activity or elimination of adenosine.[1-3]

Clinical Trials

Studies conducted in Europe,[8-9] as well as the work by DiMarco et al in the United States[5,6,10] have established adenosine's efficacy in the treatment of supraventricular tachyarrhythmias involving the AV node.

In addition, three large, multicenter trials, two sponsored by the manufacturer of adenosine, have been conducted.[3,9] The first trial was a double-blind, placebo (saline)-controlled comparison of the effects of adenosine and verapamil. One hundred thirty-one patients with spontaneous or induced SVT were randomized. Adenosine (6 and 12 mg IV bolus) and verapamil (5 and 10 mg IV dose) were effective in converting SVT to sinus rhythm in 59% and 93%, 82% and 91%, respectively, of the cases at the low and high doses. The second trial was a double-blind comparison of single IV bolus doses of adenosine versus saline placebo. If 172 patients enrolled, 137 received adenosine 6mg to 12mg. Adenosine terminated 60% and 92% of the arrhythmias respectively at the low and high doses. Saline was effective in 16% of the cases. In the recently published Adenosine for PSVT Study Group Trial, similar results were obtained for the comparison of adenosine to verapamil as well as the dose of adenosine necessary to terminate an SVT.[10]

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This series on Drug Information Updates from Hartford Hospital are provided by the Drug Information Center, Department of Pharmacy Services, Hartford Hospital.

Editors: Moses Sing Sum Chow, Pharm.D., and Robert A. Quercia, M.S., R.Ph.

Other forms of SVT, such as intra-atrial reentry, atrial flutter and atrial fibrillation, do not respond to adenosine administration, primarily because these arrhythmias do not require AV nodal conduction for their continuation. However, transient atrioventricular block and slowing of the ventricular rate have been observed with these rhythms following adenosine.[5-6] Occasionally, these rhythms may also convert to normal sinus rhythm (NSR) following adenosine, but quickly return once the effects of the drug have subsided. Ventricular arrhythmias in general are poorly responsive to adenosine, but some isoproterenol and exercise-induced ventricular arrhythmias may be terminated.[7]

Diagnostic Uses

Adenosine, in combination with electrocardiography, has also found use as a diagnostic tool in the evaluation of broad complex tachycardias, where the location of the arrhythmia is in question.[8,9] Aberrent supraventricular tachycardias involving the AV node are terminated by adenosine, whereas most ventricular tachycardias are not.

Adverse Effects

A variety of cardiovascular and non-cardiac adverse effects have been reported with intravenous adenosine.[3,11] The majority of reactions are short-lived, peaking within 30 seconds of intravenous administration and disappearing with one to two minutes. Facial flushing (18%), dyspnea (12%), and angina-like chest pressure/pain (8%) are the most frequently reported side effects.[1] Less common reactions include epigastric upset, headache, dizziness, hypotension, and numbness or tingling of the arms and neck. Patients should be reassured prior to drug administration that these uncomfortable side effects will quickly subside. Following conversion to normal sinus rhythm, a number of transient rhythms may appear, including various degrees of AV block, sinus bradycardia, sinus tachycardia, and premature atrial and ventricular contractions. Intervention is generally not necessary.

Drug Interactions

Adenosine's actions may be potentiated or antagonized by several pharmacologic agents. Dipyridamole blocks cellular adenosine transport. This increases nucleoside levels extracellularly and enhances adenosine's effects.[4,12,13] Lower doses of adenosine may be required in patients concurrently receiving this medication. Theophylline and caffeine, adenosine receptor antagonists, decrease the effect of adenosine.[4,14] Clinically, higher doses of adenosine have been required for conversion of SVT in patients taking theophylline.[3-5]

Dosage

During clinical trials, the single bolus dose of adenosine required to convert SVT in adults ranged from 2mg to 23mg (mean dose 5.8 to 13mg). Onset of effect was seen within five to 40 seconds (mean 20 seconds) following administration.[5,6,8,9] The manufacturer recommends that adenosine be given as a rapid intravenous bolus. If administered through an intravenous line, it should be immediately followed by a rapid saline flush. In adults, a 6mg bolus dose is administered initially over one to two seconds. If this dose does not terminate the SVT within one to two minutes, a 12 mg rapid bolus should be given, which may be repeated once. If the SVT does not convert following the second 12mg bolus, the etiology of the SVT must be further evaluated.[3]

Supply and Cost

Adenosine (Adenocard®, Lyphomed) is available as a 6mg/2ml (3mg/ml) injection in 2ml flip-top vials, individually packaged. Do not refrigerate. The cost of a 2ml vial is $15.05.

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HELPFUL HINTS

Cut and Sew

E. TREMAIN BRADLEY, M.D.

HOLDING a scalpel with the tips of the fingers, rather than grasping it with the whole hand wrapped around it, is common practice in the profession. But then, what determines the direction of the incision? Often it is dictated by the underlying pathology to be removed. More often there is a choice, and preference should be given to the direction of the skin lines—readily identified by pushing and pulling the skin in several directions. When an incision must be made across a joint—and this is to be avoided when possible—a Z-shaped cut when it heals and the scar contracts will still permit movement of the skin and joint, without restriction.

The method of closing a wound depends upon the tension. When the edges are reluctant to approximate, tension can be eased by horizontal mattress sutures entering well back from the edge on one side and coming out on the other side just as far back, then crossing the skin surface and entering the same side and out the first side. Sometimes the handle of the forceps passed under the skin can conveniently be used as a guide for the needle. With the tension relieved, closure can be done neatly as in wounds where the skin is relaxed.

Vertical mattress sutures have the advantage of bringing the basal layers of the skin together, resulting in less scarring. Dr. John Staige Davis of Baltimore, who, with Dr. Brown of St. Louis, started "plastic surgery" during the First World War, taught us to take a stitch through the two edges and then come back taking "one and a half cells" on each edge. Or just plain interrupted sutures may suffice.

A continuous suture can save time and be effective, either as an over-and-over stitch or as a continuing vertical mattress. However, it is important to avoid pulling the suture back toward the point of beginning, which tends to bunch the skin and shorten the line. This can be avoided by holding the ligature *up* or toward the open end. If when closure is complete the remaining length of material is short, it can be tied along with one end of an interrupted suture.

When removing sutures, the patient will appreciate it if they are cut on the distal, or denervated, side of the incision.

E. TREMAIN BRADLEY, M.D. solo practice of General Surgery, retired, Norfolk.

Letters to the Editor

SAVING MEDICAL CARE COSTS

To the Editor: In connection with Dr. Blansfield's letter, page 527, September issue *Connecticut Medicine*: Some months ago I discovered that Florida has an arrangement where retired doctors may serve a day a week or so, in a clinic provided for those unable to pay, or others who wish to avail themselves of their services. I don't know if licensure is waived, but the state pays for their malpractice insurance. It certainly gives the older doctors a chance to keep their hand in as it were, and also to help those in need of skilled medical services.

I proposed this to my state representative from the Darien district, Mr. Robert L. Jones, who has brought it to the attention of an appropriate committee. Perhaps a little nudging by other doctors would not be amiss. Speak to your state representative.

On another subject, I have found that the state will not pay pharmacists for compounding prescriptions for Medicaid patients. For example, 2% salicylic acid and 10% coal tar solution in USP hydrophyllic ointment, can be made up easily and would run the patient (state) much less than $10 I would suspect. However, I cannot have this provided for my Medicaid patients. I must order and get an expensive proprietary preparation (since there are few tars available, it is usually a steroid ointment or cream) at a considerable cost. This is really not cost effective. Perhaps someone knows how this situation can be dealt with.

Charles Sheard, M.D.

Stamford

CONFLICTS OF INTEREST IN LABORATORY USE

To the Editor: There is a lot of criticism these days in the medical literature imputing a "conflict of interest" to physicians who have their own medical laboratory to which they refer patients. It is ironic that hospital physicians whose salaries are derived in part from the profits generated by their use of the hospital's laboratory are immune from this criticism.

The point is not one of recrimination but, rather, to acknowledge that almost all physicians use medical laboratories to assist them in taking care of patients; and they all have a right to participate in any profits generated by their use of the laboratory, regardless of whether it is located outside of the hospital (as is the case with private physicians), or inside the hospital (as is the case with hospital physicians).

Those who would persist in their attacks against private ownership of medical laboratories are themselves deserving of censure for their lack of insight.

Edward J. Volpintesta, M.D.

Bethel

CSMS GROUP PURCHASING PROGRAM

The **Statewide Physician Group Purchasing Program** is a CSMS membership benef designed to reduce the expenses of office-based physicians. This voluntary program i provided at no cost to Society members through an agreement with **Connecticut Heal Institutional Services, Inc., (CHIS),** an affiliate of the Connecticut Hospital Associati

The objectives of the Statewide Physician Group Purchasing Program are:

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- To increase vendors responsiveness to our members' needs.

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Computer Consulting	Kenneth D. Margelot, Inc.	274-5333
Computer Hardware & Software	Sears Business Centers	724-7664
Forms & Stationery	Paperware Systems, Inc.	265-2288
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Medical/Surgical Supplies	General Medical Corporation	800-922-2749
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Pharmaceuticals	Henry Schein, Inc.	800-772-4346
Physicians' Desk Reference	Bookmart	914-255-5141
X-Ray Film Products/Services	E.M. Parker Co., Inc.	800-255-9177

For additional information about the group purchasing program, please call Geoffrey T. Fromme, 265-7611, X-314.

Editorial

Poverty—The Most Deadly and Prevalent of All Diseases

"Poverty—the most deadly and prevalent of all diseases." It's probably truer today than when Eugene O'Neill said it some 40 years ago. Unfortunately, cancer has been particularly cruel to our nation's poor, a primary reason why our Connecticut Division of the American Cancer Society has established a Medically Underserved Subcommittee. The hard facts bear this out.

Eight percent or 243,000 Connecticut residents live in poverty, an inordinate number of them black and Hispanic. Of all racial or ethnic groups, black Americans have the highest incidence for all cancers as well as the highest overall cancer mortality rates. Overall, the survival rate for cancer for whites is 50% but it declines to 39% and 26% for black females and males, respectively. Reasons for these unfortunate statistics vary. Studies indicate that we must increase our educational efforts inasmuch as black and Hispanic Americans tend to know less about the cancer warning signs and feel that, even if detected early, there is little chance for a cure. Less likely than whites to seek diagnosis, they are also more likely to delay or forego entirely coming back for therapy. Treatment is also delayed because many cannot afford the transportation costs and lost work.

Specific National Cancer Institute statistics are alarming. Black Americans have an especially high incidence of cancers mainly caused by smoking, including oral, lung, and larynx. They have three times the incidence and mortality rate for esophageal cancer compared to whites. Lung cancer in black males occurs 43% more frequently than in their white counterparts, while mortality is some 33% higher. For oral cancer, blacks have a 28% higher incidence rate and a 77% higher mortality rate than whites.

Equally alarming are data pertaining to black women. Black females have twice the risk of getting cervical cancer and are almost three times as likely to die from it as white females. The fact that this cancer is largely curable makes such statistics especially tragic.

The National Center for Health Statistics reports that life expectancy at birth for black Americans declined in 1986 for an unprecedented second year in a row—even as life expectancy among whites hit a new record. Black life expectancy declined to 69.4 years while white expectancy advanced to 75.4 years. Socioeconomic problems of many urban blacks, such as poverty, crime, drug use, and high infant mortality, are generally given as reasons for the decline, but smoking has also exacted a large toll.

U.S. Representative Louis Stokes (D-Ohio) has suggested that 43% of black deaths each year result from smoking-related diseases. It was reported in the *Washington Post* that blacks have a 45% greater chance than whites of getting lung cancer. Studies indicate that blacks and Hispanics suffer a disproportionate burden from cigarette smoking.

It appears obvious that the tobacco industry has been engaged in a sinister campaign for some time now to exploit a disadvantaged group of our fellow Americans. Cigarette ads now account for approximately 25% of billboard advertising. In low-income communities, one out of two billboards carry smoking messages. *Advertising Age* lists Phillip Morris as the leading marketer to the 17 million Americans who speak Spanish as a first language, according to an excellent article by Therman E. Evans, M.D. He points out how black and Hispanic publications, neighborhoods, social and political events, and community-based institutions have all been strongly supported as part of the grand tobacco strategy. America's hundreds of black and Hispanic newspapers and magazines are full of cigarette and liquor ads.

We have a gigantic educational job before us, and it is one which must have a successful ending. At all levels throughout the organization, the American Cancer Society is cognizant of and committed to addressing the special problems confronted by our poor. Connecticut, I believe, is emerging as a leader in that important effort.

Timothy B. Norbeck,
CSMS Executive Director; member Board of Directors,
American Cancer Society—Connecticut Division.

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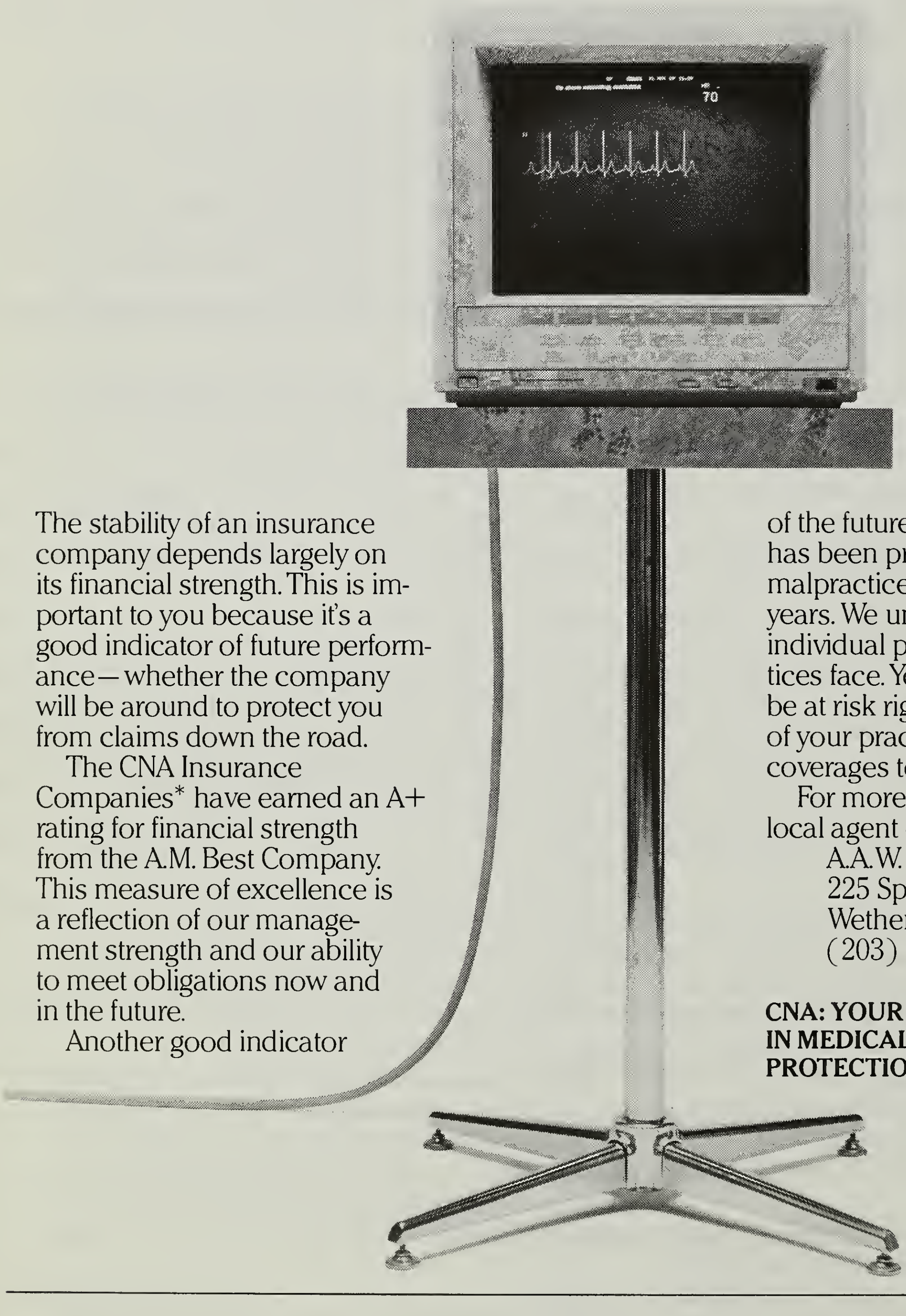

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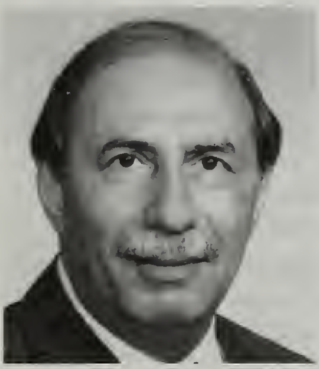
Good News: The CSMS Charitable Trust



Last year, with no fanfare or special notice, a new line appeared on your annual dues bill sent out by CSMS or by your county medical association, listing for your consideration a voluntary and tax-deductible $25 donation to the "CSMS Charitable Trust." In an effort to enhance the public image of physicians through a meaningful public service, the CSMS Council and House of Delegates had created this new corporate entity, a vehicle by which CSMS physicians can exercise civic leadership in helping to remediate adverse social conditions that impact on the health of many of our patients. Indeed, there is no shortage of outside problems that we as physicians can identify as harming the public health, such as inadequate nutrition, shelter, and education.

Of course, we recognize that most doctors already provide considerable uncompensated medical care to those in need (and get little credit for it), but this fund is intended to address *non-medical* problems that cause so much poor health in the first place. Poverty, crime, ignorance, and neglect are not topics to be found in any medical textbook, but the physical damage they do fills our emergency rooms and morgues.

Every penny you contribute to the CSMS Charitable Trust goes to helping the needy. *All* legal start-up costs and ongoing administrative costs are provided by the Society. Last year, in spite of the lack of time for prior promotion, over $15,000 was raised. The fund's first Board of Trustees then identified poor nutrition as a very basic health problem affecting the children of low-income families all over the state, and designated the Connecticut Food Bank as the first recipient of the collection. The gift was most appreciated as a commitment to relieving hunger. It facilitated the distribution of some $240,000 worth of food to where it was most needed in food pantries and soup kitchens throughout Connecticut.

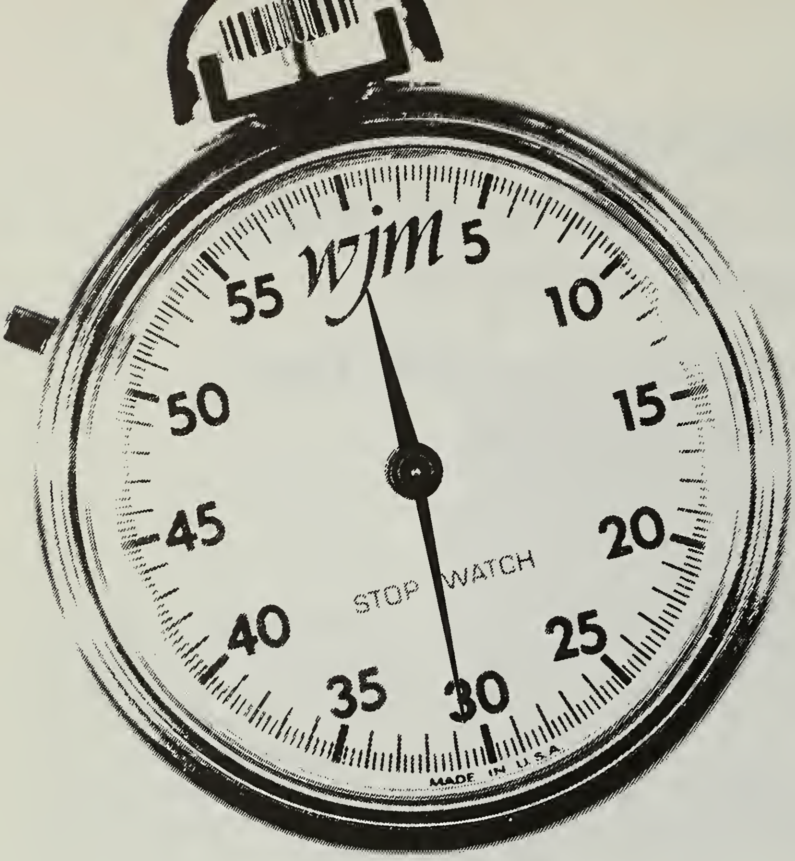
The subsequent media coverage was a bit of *good* news about doctors for a change, instead of the more typical media attacks and horror stories. The Food Bank director expressed the hope that other professional organizations would "be inspired by your trend-setting outreach."

In order to bring *more* good news about doctors to the public, CSMS will be running a series of newspaper ads in early 1991 to offer the public a set of eight new health promotion pamphlets just approved by the Society's Committee on Public Affairs. You will be receiving a sample set in the coming month, and may order a limited number of additional sets for your patients without cost. Read them over; you will like them. Sets will also go out to libraries, schools, legislators, business and industry, unions, news media, and service agencies throughout the state.

Altruism and generosity are *natural* to the healing profession, but the good that doctors do is so "oft interred with their bones." Well, we intend for CSMS to let your light shine forth, through sound health information and advice to the public, and through your 1991 CSMS Charitable Trust donations. The better your response when you mark the boxes on your dues bill in January, the greater will be the very real good that you do; the finer will be the example you will set for other professions; and the more favorable will be the impact you will foster upon the attitudes of others.

That—is *leadership.*

Mehdi S. Eslami, M.D.
President



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REFLECTIONS ON MEDICINE

Osler as Hero

ROBERT U. MASSEY, M.D.

EARLY this fall a small group of senior medical students, called "Scholars in Medicine," met in the home of one of our faculty members to talk about William Osler. One student gave a brief sketch of his life, lingering on some familiar observations on Osler's charm that had been made by his students and residents, his "breezy cheerfulness," and then told of his contributions to medicine, especially to medical education. He read from the Cushing biography and from the 1892 *Principles and Practice*. For the two faculty members this was familiar ground, but we delighted to fill in here and there with anecdotes, especially some tall tales about Osler's amazing colleague and shadow, Egerton Yorrick Davis.[1]

The discussion of Osler's life and especially the lead he had taken in the development of bedside teaching, went on and on. Students contrasted his ideal of learning in the wards with their own experience of teaching rounds, which often were little more than chart reviews, going over laboratory data and radiology reports, and maybe a quick stop at the patient's door.

> For the third- and fourth-year students, the hospital is the college; for the juniors, the out-patient department and the clinics; for the seniors, the wards. They should be in the hospital as part of its equipment, as an essential part, without which the work cannot be of the best. They should be in it as the place in which alone they can learn the elements of their art and the lessons which will be of service to them when in practice for themselves.[2]

Before this evening none of the students had heard of Osler, except the student who led the discussion and who remarked to me the next day, "I've caught the bug." Seventy years after William Osler's death, those of us who caught the bug 40 or more years ago wonder at his persisting appeal.

> Osler lives today because he was a great clinician, and because he wrote well and collected a great library, and because he had an enduring influence on colleagues and students. But his influence continues strong especially because of his humanism, a quality that resonates clearly with a contemporary resurgence in belief in the importance of humanism in restoring art to today's scientific physician.[3]

That is undoubtedly true, but as I heard these medical students warm to the topic that evening, I sensed that they, some of them, at least, were coming to feel that in this man Osler they might find their hero. They would not have said it that way for hero-worship is out of style; their word would be role model. Here was a man whose qualities, virtues perhaps, of humor, charity, commonsense, and benign humanism, might just be within their grasp. He was no Darwin or Freud to turn the world on its head, no Einstein, had not come close to winning a Nobel, and yet, though he seemed old-fashioned, he was no stranger to the work that was now beginning to fill their lives. During their three years in medical school they had all had their fill of cynical talk about medicine; here was a colleague who, by the example of his life would prove the cynics wrong.

> And lastly, the profession of medicine is distinguished from all others by its *singular beneficence*. It alone does the work of charity in a Jovian and God-like way, dispensing with free hand truly Promethean gifts. . . . We form almost a monopoly or trust in this business. Nobody else comes into active competition with us, certainly not the other learned professions which continue along the old lines.[4]

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ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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LAW, MEDICINE AND PUBLIC POLICY

The Tragic Case of Nancy Cruzan

JOSEPH M. HEALEY, J.D.

BY now, most Americans are familiar with the facts of the *Cruzan* case. In the early morning hours of January 22, 1983, Nancy Cruzan was involved in a single car accident. Apparently she had been driving too fast for the road conditions. Her car had swerved off the left side of the pavement striking some trees and a mailbox, and had swerved back across the highway, running through a fence and overturning several times before coming to rest on its top, approximately 70 yards from the previously struck mailbox. Ms. Cruzan was found lying face down in a ditch unconscious and apparently dead. Police, fire, and ambulance teams were summoned, advanced life support measures were begun, and her cardiopulmonary function was restored. Estimates of the duration of her anoxia range from six to twenty minutes, with the most likely duration twelve to fourteen minutes. She was brought to a local hospital, stabilized, transferred to a second hospital, and her initial diagnosis was listed as probable cerebral contusions compounded by significant anoxia with the prognosis hinging on the duration of her anoxia. Because of her inability to swallow significant amounts of food or water, a gastrostomy tube was surgically inserted with the consent of her then husband on February 7, 1983. Though after three weeks she apparently progressed from coma to an unspecified "unconscious state," she did not progress further and has continued to remain unconscious since the accident. A neurological examination more than five years after her accident (in the summer of 1988) concluded that she was suffering permanent and irreversible unconsciousness as a result of the anoxia caused by the original accident. Her parents, the appointed coguardians, filed suit seeking to discontinue the provision of artificial nutrition and hydration by gastrostomy tube. In 1990, this suit became the first major case decided by the United States Supreme Court dealing with decisions about level of support at the end of life.

The trial court, a Missouri Probate Court, authorized the coguardians to exercise Ms. Cruzan's constitutionally protected liberty right to seek discontinuation of the nutrition and hydration. On appeal, the Missouri Supreme Court overruled the trial court in a 5-4 decision, holding that the coguardians did not have the authority to order withdrawal of hydration and nutrition and that the evidence as to the patient's wishes was inadequate to support the claim that the coguardians were exercising "substituted judgment" on behalf of the patient.[1] In another 5-4 decision, the United States Supreme Court affirmed the Missouri Supreme Court decision holding that the United States Constitution does not prohibit a state from establishing either (1) the standard to be met in determining a patient's wishes about treatment or nontreatment, or (2) the circumstances under which family members may make decisions for other family members.[2]

Chief Justice Rehnquist delivered the opinion of the Court. He acknowledged that the principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from the Court's previous decisions. He further assumed, for the purpose of this case, that a competent person has a constitutionally protected right to refuse lifesaving hydration and nutrition. However, he emphasized that since an incompetent patient is not in the same position to exercise an informed and voluntary choice as a competent patient, a state such as Missouri was entitled to take steps to assure that the actions of a surrogate would be consistent with the wishes the patient had expressed while competent. Therefore, the requirement that the wishes of the now incompetent patient had been previously expressed in a "clear and convincing" manner does not violate the constitutional rights of the patient. Similarly, Chief Justice Rehnquist dismissed the claim that there is an obligation to accept automatically the surrogate decisions of the next of kin, emphasizing the state's interest in assuring that the incompetent patient's rights are not violated. Joining the Chief Justice were Justices White, O'Connor, Scalia, and Kennedy.

Discussion of this case will continue in next month's column.

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1. *Cruzan v. Harmon*, 760 S.W. 2d 408 (Mo. 1989).
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JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

50 Years Ago
From the *Journal of the Connecticut State Medical Society*
November 1940

Clinical Congress—1940—In Retrospect

MAURICE J. STRAUSS, M.D.
Chairman, Committee on Publicity and Registration

The sixteenth Clinical Congress, probably the most successful of them all, has come and gone.

If one can measure the success of a meeting of this sort, by the comments heard in the lobby in the intervals between lectures, it was a successful meeting. The committee has long been accustomed to hearing such remarks as; "the best ever," or "it must be good when we come back for more." This year, however, the attitude expressed by such remarks seemed to be universal. If one measures the success of a meeting by the attendance at the sessions, this was surely a success for the auditorium was comfortably crowded during all three days. And if the measure of success is to be the total registration, all doubt is dispelled. For this year produced the largest registration the Congress has ever had, for the first time reaching seven hundred.

Several factors probably cooperated to this end. We were favored with perfect weather. The program was an exceptionally well balanced and interesting one. And in addition, the program was planned so that, with the exception of the three special courses and the section meetings in the evenings, the entire meeting was held in one building. To say the program was well balanced and interesting is perhaps and understatement. The list of guest speakers was studded with the names of famous scientists who have the ability to transmit their knowledge to others. It would be tiresome to mention all of them, but certainly among the highlights were Doctor Joslin's very practical talk on Diabetes, and Doctor Blumgart's discussion of the Treatment of Coronary Artery Disease, on Tuesday. On Wednesday, Doctor Soma Weiss' extremely clear exposition of Nephritis called for very favorable comment, as did also the discussion of the Use of Estrogenic Hormones by Doctor Raphael Kurzrok. In addition the presentation of the pathological findings in cardio-renal-vascular disease, by Doctor Winternitz and his staff, was very well received. On Thursday, Doctor M. H. Dawson gave an excellent paper on Chronic Arthritis. The fact that Doctor Lahey was unable to come was somewhat of a disappointment, but was largely atoned for by the fact that doctor Marshal who took Doctor Lahey's place gave such an excellent address. Very favorable comment was heard concerning the papers of Doctor Hyman on Intravenous Drip Chemotherapy, Doctor Gold on Digitalis, and Doctor Barach on the Use of Gases in Therapy. The above are only a few of a long list of papers, each of which was extremely worthwhile.

Among the innovations was a small but interesting scientific exhibit. Doctor M. J. Schlesinger had an exhibit of hearts illustrating points brought out by Doctor Blumgart in his lecture on Coronary Artery Disease. Doctor H. E. Bacon had an exhibit of anorectal diseases, and Doctor E. Crosby had a very novel and interesting exhibit of emergency splints.

The luncheons, at each of which one of the guest speakers addressed the Congress in a question and answer session, were very well attended. The smallest number present at luncheon was one hundred and twenty two, and one hundred and seventy two attended on the day Doctor Joslin spoke.

The sixteenth Clinical Congress is history. The members of the committee, already thinking of next years Congress, have listened attentively to the comment of the members. As always, there have been some complaints, but this years program and the method of presenting it has been so well received and so well spoken of by many who attended, that the committee is encouraged to go ahead along much the same lines for next year.

From the Executive Director's Office

COUNCIL MINUTES

Wednesday, October 17, 1990

ATTENDANCE

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Beck, Blum, Bobruff, Brooks, Cottle, Dardick, Eslami, Fox, Freedman, Hollister, Kamens, Keating, McDonnell, Meridy, Orphanos, Parikh, Petrie, Redmond, Reyelt, Wetstone, and Zanker.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Garofalo, Ms. Ballou, Mrs. Connelly, Mr. Tomat (FCMA), and Mr. Coffey (HCMA).

Absent were: Drs. Ahamed, Chmieleski, Deren, Franklin, Intravia, Lesnik, Petro, Robbins, Sadowski, Sosa, Van Nostrand, Welch, and Zeppieri.

Reports of Related Organizations

CPRO: Edward A. Kamens, M.D. reported that CPRO has been selected again by the Health Care Financing Administration (HCFA) for a pilot program for the evaluation of ambulatory care. They are presently involved in a project that has to do with the collection of data in a new fashion. The ultimate purpose of this he believes is to eventually reach a point where data is gathered in a fashion that may make it unnecessary for the existence of a PRO, or at least to be a very different type of PRO where the review is conducted on a focus basis in keeping with the Institute of Medicine report presented at the AMA meeting.

A letter was presented from the CPRO Board seeking nominations to the Board of Directors. The terms of Andrew Canzonetti, M.D. and Juan Sosa, M.D. expire shortly. It was stated that Dr. Canzonetti had served two consecutive terms and was not eligible for re-election at this time. The Chairman of the Board of CPRO expressed their appreciation for Dr. Canzonetti's many contributions to CPRO, beginning with his efforts to establish the organization in 1983. Terms are for three years 1990-1993. It was VOTED to submit the names of Juan Sosa, M.D. and Roger Beck, M.D. to the Board.

CMIC: Dr. Eslami reported on a letter that had been received by CMIC from the Surgeon General of the Navy commending CMIC for waiving professional liability premiums for physicians, while they are on active duty as part of the U.S. build up in Saudi Arabia.

Report of the President

Dr. Eslami reported that he was making every effort to accept the invitations extended to him by the county associations to attend their semi-annual meetings and was also planning to attend the meeting of the Council of New England State Medical Societies. He further reported on an invitational meeting that was held by Blue Cross-Blue Shield to which leaders of the Connecticut Business and Industry Association, labor, the Hospital Association, and CSMS were invited. He and Mr. Norbeck were invited as representatives of CSMS and Dr. Gibbons of the Hartford County Medical Association was also present. The purpose of the meeting was to address the issues of the cost of health care in Connecticut. This was a preliminary meeting and another meeting has been scheduled for October 30.

Dr. Eslami discussed the forthcoming Bicentennial Celebration that would take place in 1992. Hartford and Fairfield Counties and possibly New London County will also be celebrating their Bicentennial Celebration in 1992. He suggested that all of the organizations involved should meet and cooperate with each other to make the celebration a statewide event.

As to plans for CSMS, Dr. Eslami asked that a committee be appointed, aside from the Bicentennial Celebration committee, to discuss some possible changes, etc. that could be undertaken and completed by the Bicentennial. Some of the items to be considered are the microfilming of all the historic records of CSMS, making the president's room a pictorial room of all past presidents, possible building renovations, and the acquisition of desk top publishing equipment. It was VOTED to appoint a committee as follows: Drs. Eslami, Redmond, Ahamed, Beck, McDonnell and CSMS staff. The purpose of this committee is to study and refine the suggestions outlined by Dr. Eslami and report back to the Council as to findings and costs.

Connecticut Blue Ribbon Commission on State Health Insurance

Dr. Hollister raised the question as to whether CSMS had any position on the report of this Commission, which is entitled "A Proposal to Expand Access to Health Care in Connecticut" and is chaired by Senator Cynthia Mathews. Following discussion, it was VOTED to charge the CSMS Committee on Statewide Medical Planning to review this report and prepare a position paper for CSMS that could be used before public hearings and to report back to the Council within ninety days.

Report of the Executive Director

Mr. Norbeck reviewed some of the activities going on in the political arena in Massachusetts and highlighted information on some of the candidates running for office.

He reported that he was invited to speak before the Connecticut Society of Internal Medicine executive committee on September 18 and also recently spoke before the Wallingford-Meriden Medical Society and was on a panel at Quinnipiac College.

He further reported that he was invited to serve on the CURE Board (Connecticut United for Research Excellence) to promote biomedical research.

Dr. Czarsty called for a moment of silence in honor of Mr. Norbeck's mother, who died on October 15.

Medicare Committee

A request was received from Andrew Weinberg, Chairman of the Ad Hoc Committee on Medicare, requesting that the Ad Hoc Committee be disbanded and that a standing committee on Medicare be established. The charge would be to meet on a routine basis with representatives of the Medicare carrier for the purpose of advising the carrier on issues of policy and procedures. Dr. Weinberg recommended that Paul Dolinsky, M.D., West Hartford, be named chairman. It was VOTED to approve the request and recommend to the House of Delegates to establish a standing Committee on Medicare.

1991 Budget

Following review and discussion it was VOTED to approve the 1991 Budget as presented by the Fiscal Subcommittee, and transmit it to the House of Delegates on November 28, 1990, with the Council's recommendation that the budget be approved and that the CSMS dues remain at $300.00.

CSMS Alliance With Insurance Association of America

In keeping with the new alliance between CSMS and the Insurance Association of Connecticut (IAC), the two groups are putting together a study committee to work on some of the utilization review problems. The names of three or four physicians were requested to be a part of this study committee. It was VOTED to add the following physicians to the study committee:

David W. Parke, M.D., Meriden (NH)
David H. Hild, M.D., Hartford (H)
John F. Pezzimenti, M.D., Danbury (F)
Ellen R. Fischbein, M.D., Cheshire (NH)

AMA Activities

Stewart Petrie, M.D. asked that if members of the delegation or Council had any items they wished discussed at the forthcoming meeting of the Council of New England State Medical Societies, he asked that they be forwarded to him as soon as possible. Dr. Petrie thanked Dr. Kamens for providing the AMA delegation with a Connecticut logo, which he had designed and paid for which could be affixed to the delegates' jackets. These logos have been exhausted and Dr. Petrie asked the Council for approximately $200 to get a new supply of these logos. It was VOTED to approve this request.

Patient Care Quality Standards for Alcohol and Drug Related Trauma

At a recent Council meeting, it was VOTED to accept a report by the CSMS Committee on Public Health on Patient Care Quality Standards for Alcohol and Drug Related Traumas for study and consideration. The report was referred to the CSMS Committee on Emergency Medical Services for their advice and consultation with a request that the findings be reported back to the Council. The Council reviewed the critique of the Committee on Public Health's report and VOTED to refer the EMS critique back to the Committee on Public Health for their consideration and report.

Legislation

Howard Wetstone, M.D., Chairman of the Committee on National Legislation, reported on the following items:

(1) *Neo-Natal Beds:* Two meetings were held with Dr. Foye, Chairman of the CSMS Committee on Perinatal Morbidity & Mortality and various obstetricians and pediatricians concerning the need for more neonatal intensive care beds. It was reported that there was no hard data to accurately evaluate the need for more neonatal intensive care beds, however, there was definitely a perceived need expressed by the obstetricians and pediatricians throughout the state. Dr. Wetstone stated that all of the hospitals with neonatal nurseries were interdependent and worked well together. It was VOTED to approve the recommendation of the Committee on Legislation that CSMS request the Committee on Perinatal Morbidity and Mortality to develop the cost of a complete and unbiased study of neonatal and maternal service needs in Connecticut and report back to the Council as to procedure and costs.

(2) *Issues for the 1991 Legislative Session:* Dr. Wetstone reviewed the following list of issues that may surface in the 1991 legislative session which the committee approved for recommendation to the Council:

- Support tougher drunk driving laws.
- Support tougher helmet laws.
- Oppose any negative changes in the present physician health protocol with the state.
- Support tougher laws to ban smoking.
- Oppose any decrease in the number of mental health beds and investigate submitting legislation to increase the number of mental health beds.
- Support firearm control legislation.
- Oppose any allied health profession group's attempt to invade a physicians practice area, including but not limited to - opposing the use of therapeutic drugs by

optometrists, opposing direct access for physical therapists and opposing hospital privileges for psychologists.

- Support a reduced licensing fee for retired physicians.

During the discussion the issues of the hassle factor, managed care, parody in Medicare and Medicaid payments were raised with the suggestion that the Committee on Legislation keep abreast of these issues. It was VOTED to approve the list of recommendations proposed by the committee.

(3) *Candidate Package:* It was VOTED to approve the recommendation of the Committee on Legislation that CSMS produce a package for newly elected legislators with a letter of congratulations as well as the new public affairs brochures and to invite them to a cocktail reception that could possibly be held after the House of Delegates meeting in November.

(4) *Coalition on Children:* It was VOTED to approve the recommendation of the committee that CSMS join the Coalition on Children, which is a group which is concerned with children's health in the state.

Life Members

It was VOTED to receive as information the names of the following physicians who were granted Life Membership as of 1/1/90:

William Braisted, M.D., Branford (NH)
John B. Morrison, M.D., Orange (NH)

Date of Next Council Meeting

Thursday, January 10, 1991

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on October 17, 1990. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested members of the Society.*

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COMMITTEE SERVICE QUESTIONNAIRE

Connecticut State Medical Society

Early in 1991 the Councilors from the eight constituent county medical associations assume the responsibility of selecting members of the Society to participate in the various activities of the Society listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, all members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

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☐ Committee on Ethical and Judicial Affairs

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☐ Committee on Public Affairs

Scientific and Socio-Environmental Medicine

☐ Committee on Emergency Medical Services
☐ Cancer Coordinating Committee
☐ Committee on Physician Health
☐ Committee on Maternal Morbidity and Mortality
☐ Committee on Medical Aspects of Sports
☐ Committee on Mental Health
☐ Committee on Organ and Tissue Transfers
☐ Committee to Study Perinatal Morbidity and Mortality
☐ Committee on Public Health
☐ Committee on Statewide Medical Planning
☐ Committee on Geriatrics

Representative and Advisors

☐ Joint Practice Committee
☐ Committee on Allied Health
☐ Committee on Cooperation with the Medical Schools of Connecticut
☐ Liaison Committee with Connecticut Pharmaceutical Association
☐ Liaison Committee with State Department of Income Maintenance
☐ Representatives to Connecticut Advisory School Health Council
☐ Delegates to Connecticut Public Health Association, Inc.
☐ Delegates to Connecticut Nutrition Council

Please return by January 20, 1991

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(Please Print)

Office Address: ________________________________

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a free service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to Physician Placement Service, Connecticut State Medical Society, 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

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FP/INTERNIST—BE/BC sought for Southern Fairfield County Community. Opportunity to share established group practice. Salary/benefit package, including malpractice. Start 1991. Send letter of interest and CV to: CSMS, c/o FP/KO.

GENERAL PRACTICE/INTERNAL MEDICINE

Physician needed for general practice or internal medicine. Location: Hilliard Bldg., Manchester, CT. Phone 1-649-4838 or 1-226-4456.

INTERNAL MEDICINE

Grove Hill Medical Center—BC/BE internist to join satellite office of 56-physician multispecialty group in Central Connecticut. Experience in women's health care preferred. University-affiliated hospital and teaching opportunities. Position available June 1991, affords opportunity for association within one of the East Coast's oldest and most respected group practices, generous salary and benefits, and earned partnership status. Interested candidates should forward CV to: Kenneth T. Johnson, M.D., CEO, Grove Hill Medical Center, 300 Kensington Ave., New Britain, CT 06051.

Grove Hill Medical Center—BC/BE internist to join 56-physician multispecialty group in Central Connecticut. University-affiliated teaching program. Position available June 1991, affords opportunity for association within one of the East Coast's oldest and most respected group practices, generous salary and benefits, and earned partnership status. Interested candidates should forward CV to: Kenneth T. Johnson, M.D., CEO, 300 Kensington Ave., New Britain, CT 06051.

Associate pulmonary specialist sought to work with three established, board certified pulmonologists. Opportunity to work exclusively in pulmonary medicine in Meriden-Wallingford-Southington Connecticut areas in community hospitals. Additional opportunities available in nearby facilities. Please contact Richard Smith, M.D., (203) 238-8235.

BC/BE internist to replace retired physician. Opportunity to build own practice; share office, expenses, and coverage. Please send CV to George Burton, M.D., 488 Montauk Ave., New London, CT 06320.

Internist, with or without subspecialty, to associate with internist/cardiologist. Open both to established practitioners and those fresh from residency or fellowship. Begin anytime up to July, 1991. Send CV to Jonathan Greenwald, M.D., 148 East Ave., Norwalk, CT 06851-5734; Tel: (203)866-7000.

Small private practice in Greater Hartford area looking for internist. BC/BE. Salary plus bonus and partnership potential. Affiliated with local hospital. Great growth potential. Available immediately. Call (203)676-0680 or send CV to : Devra Sisitsky, Suite 103, 302 West Main St., Avon, CT 06001.

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Coronary Artery Bypass Plus Mitral Valve Replacement

A Five-Year Study

STUART L. HOUSER, M.D., FAYYAZ H. HASHMI, M.D., TIMOTHY L. LEHMANN, M.D., THOMAS K. KALMBACH, M.D. AND SURENDRA K. CHAWLA, M.D.

ABSTRACT—Fifty-two patients with a mean age of 67.6 years underwent coronary artery bypass plus mitral valve replacement from 2 April 1984, through 6 February 1989. All but four of these 25 males and 27 females were in the New York Heart Association Functional Classes III and IV, with presenting symptoms of angina and/or dyspnea. Twenty-four patients (44.2%) presented with acute myocardial infarctions, and eleven patients (21.2%) had a past history of rheumatic fever or rheumatic heart disease. Forty-five patients (86.5%) had a diagnosis of coronary artery disease plus mitral regurgitation. Treatment included a mean of 2.3 bypass grafts per patient plus mitral valve replacement with Carpentier-Edwards (41), St. Jude (10), and Bjork-Shiley (1) prostheses. The four operative deaths (7.7%) were attributed to congestive heart failure (1), mediastinal bleeding (1), mediastinitis (1), and stroke (1). There were eight late cardiac deaths (16.7%) and six late noncardiac deaths (12.5%), a mean of 16.6 and 18.9 months postoperatively, respectively. Thirty-four patients have survived from 10 to 65 (mean 33.7) months postoperatively with a mean New York Heart Association Functional Class 1.6. Follow-up determination of patients' attitudes toward their surgery was ascertained in 28 of the 34 survivors, and 26 (92.8%) patients indicated that they were pleased with their surgery.

These results compare favorably with data reported in the recent literature. In addition, the study shows that patients requiring supportive treatment in a critical care unit preoperatively had the same operative mortality but more postoperative complications and a longer mean hospital stay than the equal number of patients who were not in a critical care unit preoperatively. Strict attention to myocardial preservation is stressed as the technical measure of success in this complex operative procedure.

IN 1981 Kennedy, et al,[1] reported the findings of the Collaborative Study in Coronary Artery Surgery that the operative mortality rate for combined coronary artery bypass plus mitral valve replacement procedures done at 15 institutions from 1975 to 1980 was 23.7%. The purpose of this communication is to examine the results of operating on these sick patients at the present time with a strict and standardized technique of myocardial preservation. A recent five-year experience with patients undergoing this complex surgical procedure in a private practice setting is reviewed. These results are then compared to similar groups of patients reported in the current surgical literature.

Material and Methods

Fifty-two patients underwent coronary artery bypass plus mitral valve replacement form 2 April 1984 through 6 February 1989. These 25 males and 27 females ranged in age from 43 to 84, with a mean of 67.6 years. Three patients complained of angina, 20 had dyspnea, and 29 presented with both symptoms. Twenty-six patients were in New York Heart Association functional Class IV, 22 were in Class III, and four were in Class II. Half of the patients were hypertensive, and almost one-third were diabetic. About 15% of the group had a history of cerebral vascular insufficiency, and 21% presented with a history of rheumatic fever and/or rheumatic heart disease.

Thirty-seven patients (71.2%) had a history of myocardial infarction. Nineteen patients had had an old infarct,

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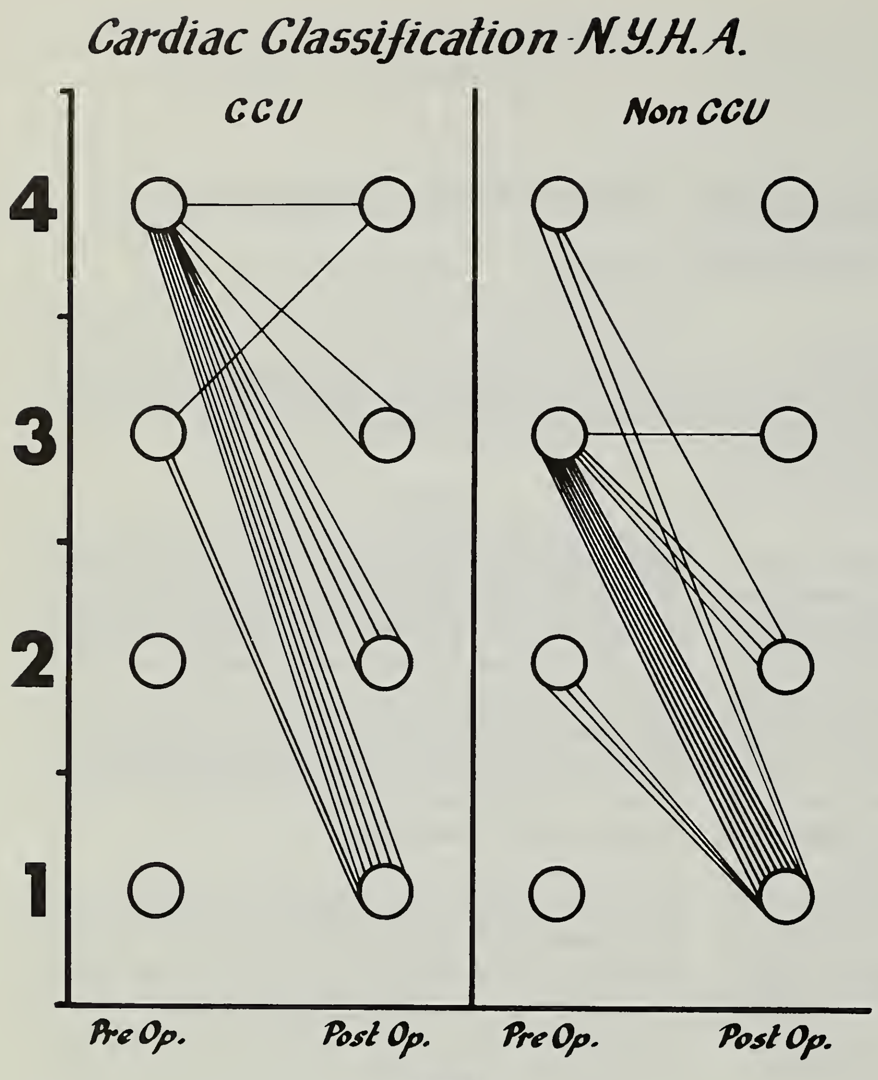

Figure 1

and 23 developed a myocardial infarction within four weeks of their admission to the hospital. Almost half of these acute infarcts were non-Q wave injuries. The acute transmural infarcts were in the inferior, lateral, and/or posterior wall of the heart.

Coronary angiograms documented triple vessel coronary artery disease, ie, 60% or greater stenosis in the right and left anterior descending and circumflex systems in 27 patients. Double vessel disease and single vessel disease were seen in 14 and 11 patients, respectively. Significant left main coronary artery disease was found in four patients. Mitral regurgitation in most cases was graded 3-4+.

Forty-five patients (86.5%) had coronary artery disease plus pure mitral insufficiency. Of these, one patient had had a previous coronary artery bypass, two had had mitral valve replacement, and one had had coronary artery bypass plus mitral valve replacement. Five patients presented with coronary artery disease plus mitral insufficiency and mitral stenosis, one with a previous open mitral commissurotomy, and one with a previous closed mitral commissurotomy. Two patients presented with coronary artery disease plus mitral stenosis alone, one of whom had had a previous closed and subsequent open mitral commissurotomy.

The surgical procedures were done using standard ascending aortic and bicaval cannulation to institute cardiopulmonary bypass with moderate systemic hypothermia. Myocardial preservation was achieved by infusing cold crystalloid potassium cardioplegic solution into the aortic root and/or vein bypass grafts in order to keep myocardial temperatures below 20°C. The mean number of bypass grafts per patient was 2.3. Forty-one patients (78.8%) had saphenous vein grafts only. Two patients had internal mammary grafts only, one with bilateral internal mammary artery grafts and one, a sequential internal mammary artery graft. Nine patients had a combination of internal mammary artery plus saphenous vein grafts. Forty-one patients received Carpentier-Edwards porcine valve protheses; ten St. Jude, and one Bjork-Shiley valve protheses were placed.

Table 1
Coronary Artery Bypass & Mitral Valve Replacement Postoperative Complications

	N		N
Arrhythmia		Bronchitis/Pneumonia:	2
- Supraventricular:	28	Pleural effusion:	2
- Ventricular:	14	Pericardial effusion:	1
- Junctional:	3	Gastrointestinal bleeding:	2
Congestive heart failure:*	9	Fever of unknown origin:	1
Pulmonary insufficiency:	8	Leg neuropathy after IABP:*	1
Acute renal failure:	7	Pneumothorax:	1
Mediastinal bleeding:*	2	Sacral decubitus:	1
Mediastinitis:*	1	Leg wound infection:	1
Stroke:*	1	Sepsis	2
Transient ischemic attack:	1	Oral herpes/thrush:	2
Encephalopathy:	4	Anxiety neurosis:	1

*Cause of death in one patient

*Intra-aortic balloon pump

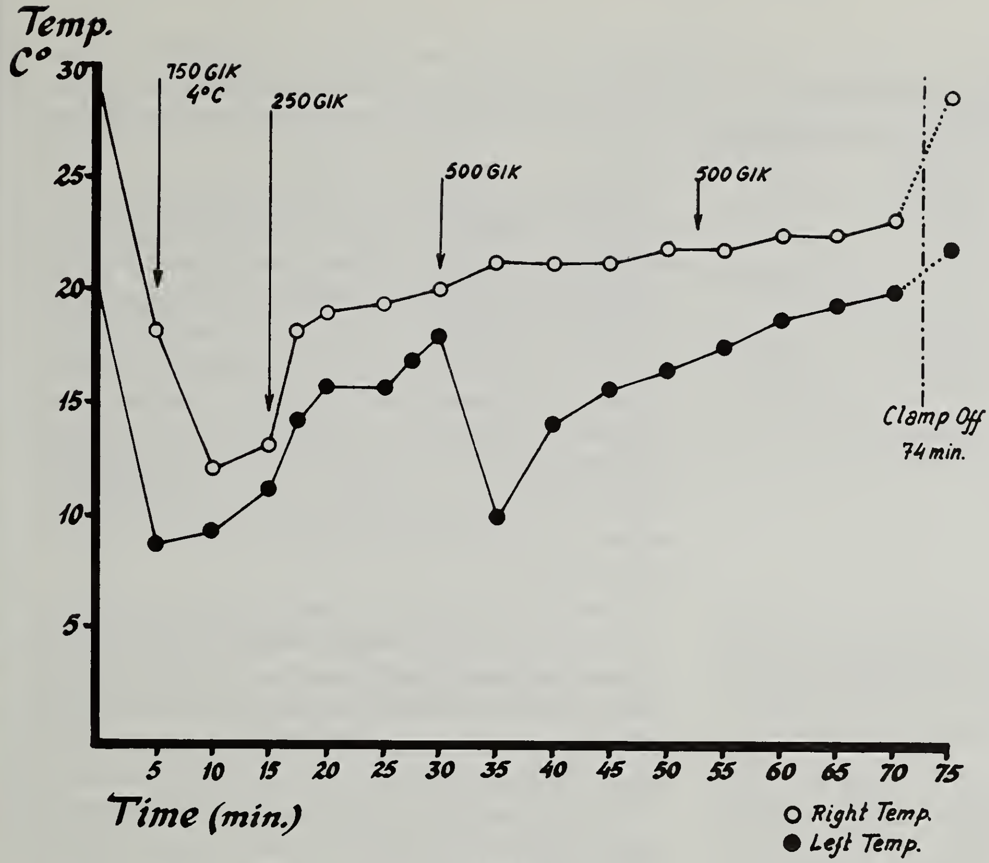

Figure 2

Results

Two-thirds of the patients demonstrated myxomatous change in their mitral valves. Fibrosis and calcification were found in the valves of 19 and 10 patients, respectively. Papillary muscle infarction was demonstrated in nine valve specimens. Five specimens showed changes of old rheumatic valvulitis, and five had focal endocarditis. Both patients undergoing a second mitral valve replacement had torn leaflets in their old valve prostheses.

There were four operative deaths (7.7%) in the group. Three of these deaths occurred within 30 days of surgery, the fourth patient was discharged from the hospital six weeks postoperatively, was readmitted one day later in congestive heart failure, and died in the hospital about one month later. The postoperative hospital stay of the survivors was six to 41 (mean 14.9) days.

Nine patients had no postoperative complications; excluding arrhythmias, another 18 patients were free of postoperative complications. Table 1 lists complications encountered in these patients, including the causes of death in the four patients who did not survive their operations.

Half of the patients were in a critical care unit (CCU) prior to their surgery. Table 2 lists the supportive measures required by this subgroup of patients. The average age and presenting symptoms of these patients were similar to those of patients not requiring preoperative critical care unit support. Eighty-one percent of critical care unit patients were in New York Heart Association Class IV preoperatively, whereas in the noncritical care unit subgroup only 19% were Class IV. The patients presenting with acute myocardial infarcts were predominently in the CCU subgroup. Of the 11 patients presenting with the history of rheumatic fever and/or rheumatic heart disease, four were in the CCU preoperatively and seven were not. The mean number of coronary artery bypass grafts per patient, the number of repeated procedures, and the number of patients with documented papillary muscle infarction were about equally represented in

Table 2
Coronary Artery Bypass & Mitral Valve Replacement

Preoperative CCU Support	Number of Patients
Total:	26 (50%)
Monitoring Line(s)[a] Only:	8
Intravenous Drip(s)[b] Only:	3
Line(s) & Drip(s):	15
Intraaortic Balloon Pump:	8[c]
Ventilator:	2
Intraaortic Balloon Pump & Ventilator:	1

a - Arterial line and/or Swan-Ganz catheter
b - Nitroglycerin and/or pressor agent, except for one patient with Lidocaine only
c - Two additional patients had postoperative intraaortic balloon pump

Table 3
Coronary Artery Bypass & Mitral Valve Replacement

	CCU Patients	Non-CCU Patients	Total
Study Group:	26	26	52
Operative Deaths:	2 (7.7%)	2 (7.7%)	4 (7.7%)
Postoperative Hospital Stay of Survivors (Days)	8-41 ($\overline{19.2}$)	6-29 ($\overline{10.6}$)	6-41 ($\overline{14.9}$)
Postoperative Complications:			
- Cardiac:	29	27	56
- Noncardiac:	27	10	37
- None:	4	5	9

Table 4
Coronary Artery Bypass & Mitral Valve Replacement Follow-Up Results

	CCU Patients	Non-CCU Patients	Total
Follow-up Group:	24	24	48
Cardiac Deaths:	5	3	8 (16.7%)
- Months postop	5-24 ($\overline{10.1}$)	4.5-52 ($\overline{23.2}$)	$\overline{16.6}$
Noncardiac Deaths:	3	3	6 (12.5%)
- Months postop	6.5-28 ($\overline{16.5}$)	5-36 ($\overline{21.3}$)	$\overline{18.9}$
Survivors:	16	18	34 (70.8%)
- Months postop	11-65 ($\overline{33.7}$)	10-61 ($\overline{33.7}$)	$\overline{33.7}$

both subgroups. The operative mortality rate in each subgroup was the same. Both operative deaths in the CCU patients had preoperative intraaortic balloon pumps, and one of these patients was also intubated preoperatively.

The postoperative hospital stay of the survivors was longer in the CCU subgroup of patients. The number of postoperative cardiac complications was about the same in both subgroups; however, the cardiac complications in the CCU subgroup were more serious than in the other subgroup and were related either directly or indirectly to their greater number of noncardiac complications (see Table 3). Follow-up results are illustrated in Table 4. Two late cardiac deaths occurred in patients that had required preoperative intraaortic balloon pump support, one preoperatively and one postoperatively. Therefore, six of 10 patients who had required perioperative intraaortic balloon pump support are among the long-term survivors. The operative survivor who had required ventilator support without balloon pump preoperatively died of cardiac causes about five months following his surgery. The long-term survivors had a mean New York Heart Association functional class of 3.4 preoperatively, and 1.6 postoperatively (see Fig. I), with a mean follow-up of 33.7 months. This improvement in functional class is reflected by the finding that 26 of the 28 patients (92.9%) whose attitudes regarding their surgery are known indicated that they were pleased that they had had their operations.

Discussion

Within our total cardiac experience (see Table 5), this report deals with a small group of older patients with a relatively high operative mortality rate. However, the results of this study indicate a distinct improvement in operative mortality rate (7.7% vs 23.7%) over the results of the Collaborative Study in Coronary Artery Surgery published nine years ago.[1] Furthermore, these results compare favorably to those of similar groups of patients reported in the current literature (see Table 6),[2-9] which also demonstrate substantial improvement in operative survival when compared to the results reported a decade ago.

Although coronary artery bypass plus mitral valve replacement appears to be accomplished more safely now than in the past, some authors[7,8] emphasize that patients with ischemic mitral valve disease have a higher operative mortality rate than those with nonischemic valve disease. Furthermore, Tsai, et al,[9] as well as this report to a lesser extent (see Table 6), show a relatively high operative mortality rate in septuagenarians and octogenarians compared with younger patients undergoing this surgical procedure. This finding is not surprising to these authors in view of their recent report on cardiac surgery in octogenarians.[10]

In conclusion, this study reports an acceptable outcome in patients undergoing coronary artery bypass plus mitral valve replacement. No difference was found in operative mortality rates of patients who were in a CCU setting preoperatively when compared to the operative mortality rates of those who were not. However, the hospital stay of the former group does appear to be longer because of a greater number of postoperative complications. The patients requiring intubation preoperatively and/or intraaortic balloon pump support for treatment of congestive heart failure did not do as well as less sick patients, although the numbers are too small to be conclusive.

It is important to the success of this operation to emphasize the need for strict attention to techniques of myocardial preservation.[11] The surgeon must be compulsive about keeping both the right and left heart chambers cold during the aortic clamp time, which may be prolonged by the technical requirements of this combined procedure. We have observed that with aortic root installation of the cardioplegic solution, right ventricular temperature may be higher than the left ventricular temperature (see Fig.

Table 5
Total Cardiac Experience

Year	Total Patients	Operative Mortality Rate(%)	Mean Age (Yrs.)
1984	415	2.7	62.7
1985	524	4.2	62.7
1986	585	2.6	62.4
1987	549	2.9	64.3
1988	592	3.0	64.0
1989	638	3.6	65.0
TOTAL:	3303	MEAN: 3.2	MEAN: 63.5

Table 6

Coronary Artery Bypass & Mitral Valve Replacement

Author, Et Al	N	Mean NYHA	Study Period	OP. M.R.	Late Cardiac Deaths	Late Survivors	Follow-up (Month's)	Mean NYHA
Lytle - 1985	300	2.9	1970-83	7.3%	87 (31.3%)	179 (64.4%)	2-165 ($\overline{48}$)	1.2
Magovern - 1985	28		1977-82	17.9%				
Bergdahl - 1986	44		1975-85	9.1%	8 (20%)		6-120 ($\overline{31}$)	
Andrade - 1987	76	3.5	1979-84	13.2%				
Cohn - 1988	21		1984-87	4.8%				
Houser - 1990	52	3.4	1984-89	7.7%	8 (16.7%)	34 (70.8%)	10-65 ($\overline{33.7}$)	1.6
Tsai - 1986	38[a]		1980-84	50. %				
Houser - 1990	23[a]	3.5	1984-89	17.4%	5 (26.3%)	13 (68.4%)	10.5-65 ($\overline{37.7}$)	1.4

[a]-70 and 80 year-olds

II). If right and left ventricular temperatures are not monitored simultaneously, this gradient will not be recognized. Inadequate preservation of the right ventricle, resulting in right ventricular failure, has been addressed by one of us (SKC) as a lethal complication in combined coronary artery bypass plus mitral valve replacement.[12]

When the mitral valve is exposed by vigorous retraction, the ascending aorta is distorted and effective administration of cardioplegic solution into the aortic root is difficult to maintain. However, if cardioplegic solution is instilled into the vein grafts after they are sewn to the coronary arteries this temperature gradient can be eliminated. These authors have been pleased with their ability to keep the heart cold with repeated doses of cardioplegic solution through multiple vein grafts while the mitral valve is exposed.

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A Comparison of Ground Paramedics and Aeromedical Treatment of Severe Blunt Trauma Patients

ROBERT J. SCHWARTZ, M.D., M.P.H., LENWORTH M. JACOBS, M.D., M.P.H.,
AND RICHARD J. JUDA

ABSTRACT—This study compared a hospital-based aeromedical program to a ground paramedic service in order to determine whether the element of prehospital time or prehospital care is the major contributor towards improved survival.

One hundred twenty-six severe blunt trauma patients were studied. There were 93(73.81%) transported by air and 33(26.19%) transported by ground. Utilizing the TRISS methodology, the air patients had a probability of survival of 2.23 SD better than the national norm, and the ground patients had a -2.69 SD below the national norm. The air patients had a higher percentage of intubated patients (42% vs 3%) and use of PASG(56% vs 30%). There was no significant difference in the prehospital times of either the air or ground services once they had arrived at the scene. Since the scene time of both services is similar, the improved survival of the air patients may be due to the technical intervention procedures performed.

Introduction

THE Emergency Medical Services (EMS) System in Connecticut has expanded and improved over the last decade.[1] Sixty percent of the state's population now has paramedic coverage and all the regions can be reached by the LIFE STAR critical care ambulance program since its inaugural flight in June 1985. As the EMS system matures, the level of care and complexity of the intervention becomes greater. The evaluation of the benefits of the care is a necessary component to maintain quality of care and to identify treatment and services that benefit the patient.

Previous research has shown that the LIFE STAR critical care helicopter[2] improved survival in trauma patients involved in motor vehicle collisions when compared to ground ambulance transported trauma patients. That report identified two factors that may be responsible for the improved survival. They are the level of care delivered and the prehospital time, defined as the length of time from the injury to arrival at a trauma center. However, that study did not include the prehospital time and therefore, could not determine which factors were associated with improved survival.

The purpose of this report is to compare LIFE STAR to ground paramedics in order to determine whether the element of prehospital time or prehospital care is the major contributor to the improved survival in Connecticut.

Materials and Methods

All multisystem injured trauma patients from vehicular collisions who were transported directly from the scene of the injury to Hartford Hospital between 1 July 1987 and 30 June 1988 were eligible for inclusion in this study. Only patients treated by ground paramedics or LIFE STAR were included. The LIFE STAR crew consists of a flight physician, flight nurse, flight respiratory therapist, and pilot. Paramedic ambulances are staffed with a mini-

Table 1
A Comparison of Prehospital Skills

Paramedics	**Life Star**
Oral intubation	Oral/Nasal intubation
IV peripheral	IV peripheral/femoral
PASG	PASG
———	Cricothyrodotomy
Needle decompression	Needle decompression
Cardiac medications	Cardiac medications
Valium, MS	Muscle relaxants
Cardiac monitor	Cardiac monitor
———	Chest tubes
———	NG tubes

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mum of one paramedic and one other emergency medical technician (EMT). Data were obtained by reviewing information from three separate computerized data management registries and medical records.

These computerized registries contain data regarding LIFE STAR, paramedics, and trauma patients received by Hartford Hospital. The paramedic and LIFE STAR registries contain data from each hospital sponsored service. These data include the prehospital times, interventions (Table 1), and individuals who performed the procedures. The trauma registry contains inpatient information. This includes inpatient number, medical record number, age, length of stay, and charges. Finally, the patient's chart was reviewed for outcome and confirmation of registry data.

Table 2
Time Element Calculations

Response time = Scene arrival time—Injury time
Scene time = Enroute time—Scene arrival time
Time to hospital = Hospital arrival time—Enroute time
Prehospital time = Hospital arrival time—Injury time

Data elements collected were age, sex, mode of transport, mechanism of injury, prehospital times, medical interventions, trauma score (TS), injury severity score (ISS), and outcome. Prehospital times are represented in Table 2. Paramedic run times were recorded by each paramedic. To obtain the approximate time of injury, the initial dispatch time for medical assistance was used. In an urban EMS environment, notification of authorities occurs close to the time of the actual motor vehicle collision. The LIFE STAR prehospital times were obtained from the LIFE STAR registry. These times are recorded by the flight dispatcher during the actual mission. The time of injury is obtained at the scene from scene personnel.

Data from all registries were combined and examined. Comparisons were made between the LIFE STAR treated patients and the paramedic treated patients on the frequency of successful interventions such as intubation, intravenous therapy and PASG. Statistical differences in success rates were measured using a chi-square analysis. An analysis of the prehospital times was performed between the two groups utilizing the t test.

The two groups were then compared for differences in physiologic and anatomic scores. TS,[3,4] injury severity score,[5,6] and probability of survival were compared using the t test. Utilizing the trauma score injury severity score (TRISS) methodology of the Major Trauma Outcome Study,[7] the predicted survival (Ps) of the groups was compared to the observed survival.[8] The TRISS methodology is a statistical method for comparing performance with a national data base of more than 40,000 patients.

Table 3
Success of Interventions by Service

Fields	Life Star	Paramedics
Number of patients	n=93	n=33
Intubation	n=41(41.83%)	n=1(3.03%)
PASG	n=52(55.91%)	n=10(30.30%)
Peripheral IV #1	n=79(84.94%)	n=26(78.79%)
Peripheral IV #2	n=33(35.49%)	n=1(3.03%)

Results

One hundred twenty-six patients were entered into the study. Ninety-three (73.81%) were transported by LIFE STAR and 33 (26.19%) were transported by ground paramedics.

The LIFE STAR patients had a calculated probability of survival of 2.23 SD better than the national norm. This is a statistically significant improvement in mortality. The ground paramedics had a calculated probability of survival of -2.69 SD below the national norm.

Table 4
Response Times

	Life Star	Paramedics
Average response time	34.41 min	5.67 min
Average scene time	22.13 min	18.45 min
Average time to hospital	9.59 min	10.75 min
Average total prehospital time	65.24 min	33.72 min

Interventions performed by the ground paramedics had a lower incidence of success than those performed by the LIFE STAR crew (Table 3). The TS for the LIFE STAR patients was 10.81. The TS for the ground patients was 12. Comparison showed that the LIFE STAR patients had significantly lower TS ($t= 10.81$ $p<0.05$). The mean ISS for LIFE STAR patients was 30, for ground patients the mean ISS was 21($p=0.05$). There was no difference in the survival between the two groups; 24 ground patients survived (72.7%) and 67 air patients survived (72.0%).

Table 4 shows the distribution of the total prehospital time for LIFE STAR and ground paramedics. There is no difference between the prehospital times in the two groups once they have arrived at the scene. The time at the scene and the time to transport to the hospital are not statistically different; however, there is a significant difference in the time of arrival at the scene after the injury. The mean ground paramedic response was 5.67 minutes and the mean LIFE STAR response to the scene was 34.41 minutes after the injury had occurred.

Discussion

This study compared the performance associated with two prehospital care provider groups, ground paramedics and an aeromedical crew, in an attempt to identify determinants of care that have improved survival.

Patients treated by LIFE STAR were significantly more likely to survive than those patients treated by ground paramedics. This is in keeping with previous reports; however, it was surprising to find that the patients treated by the ground paramedics had a lower survival rate than would have been expected from national data. This study was not able to explain the reason for this, but a lower rate of successful interventions may be directly related to the poorer survival. Intubation, rather than pneumatic anti-shock garments (PASG) or intravenous catheters would have the greatest effect on survival in these trauma patients.

Evaluation of the prehospital times shows that air and ground ambulance scene times are not statistically different. One can infer then that the improved survival as mentioned above is due to the higher skill level of technical intervention, such as intubation.

Another observation is the much longer time from injury to arrival of LIFE STAR. This extended prehospital time may be due to a delay by the first responders to recognize the need for the aeromedical intervention or hesitation in calling. Based on these data and previous data, this hesitancy cost lives.

This study examined one group of paramedics, and was not a state-wide or EMS system-wide evaluation. Generalization of these data to all paramedic services is not possible. Since all patients were transported to the same trauma center, these results cannot be generalized to other trauma centers in the state.

We recommend a comprehensive, statewide analysis of trauma care be undertaken to identify the strengths and weaknesses of our trauma care system. This study suggests that paramedics who care for relatively small numbers of severely injured patients may not have adequate skill maintenance. A statewide injury surveillance system would help to identify those parts of the trauma care system that need improvement through education and skill maintenance. We have shown that over a three-year period the LIFE STAR crew has been able to maintain their skill levels and improve survival. Earlier decisions to call LIFE STAR so as to reduce response time should further enhance survival rates.

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Important Advances in Clinical Medicine

Ophthalmology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in ophthalmology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in ophthalmology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Ophthalmology of the California Medical Association, and the summaries were prepared under its direction.

Recent Developments in Radial Keratotomy

RADIAL keratotomy is a surgical procedure designed to correct nearsightedness (myopia). During the procedure, the surgeon uses a diamond-bladed micrometer knife to make spoke-like partial-thickness radial cuts in the paracentral and peripheral cornea to produce corneal flattening, which reduces myopia. In the early 1980s the operation was growing in popularity but had not been formally tested. In 1981 the National Eye Institute funded the Prospective Evaluation of Radial Keratotomy (PERK) Study to investigate the safety and efficacy, predictability, and stability of radial keratotomy. The PERK results and those of other studies have shown that almost all patients become less myopic with few serious complications. Those with less myopia had better results four years after the procedure. Approximately 75% of patients in the PERK study had 20/40 vision—unrestricted driver's license vision—or better without glasses, and 64% wore no optical correction. The predictability of results for an individual patient has been less than desired, however. New technology and surgical techniques are improving the predictability, and, as a result, about 80% of operated eyes now fall within the ± 1.00 diopter range, the ideal result being mild residual myopia (-0.50 diopters).

Based on results reported to date, the relative safety of radial keratotomy is documented. Severe vision-threatening complications have been rare, and the most common complications, although not insignificant, have been a loss of two or three Snellen lines of best corrected visual acuity. This occurred in 2.5% of the patients in the PERK study at four-year follow-up.

Surgeons doing radial keratotomy previously used 16 or more incisions; the PERK study used 8, and many surgeons are currently using 4 initial incisions. If an undercorrection occurs, the original incisions can be lengthened or deepened, or additional incisions can be added. Further studies will be required to examine the effectiveness of these techniques in improving predictability.

All of the major radial keratotomy studies have reported the phenomenon of a continued progressive effect of the surgical procedure in some patients. From 15% to 31% of patients' operated eyes have had a continuing decrease of -1.00 diopter or more—a change toward farsightedness—from one to four years after the operation. There is speculation that this is associated with wound healing, and some data support an association between an incisional depth of greater than 90% of corneal thickness and instability. Follow-up results beyond five years will provide useful information regarding this problem.

In the longer term, two technologic applications may improve radial keratotomy results and its predictability. By the use of finite-element computer simulation of the cornea, the theoretic results of radial keratotmy can be studied. The correlation of theoretic and experimental results will lead to a better understanding of the biomechanics of the cornea and to better surgical techniques. In addition, computerized imaging of the corneal shape videokeratography, allows more detailed study of the optical properties of the cornea after the surgical procedure.

The second new technology is using excimer lasers to do corneal operations. Two strategies that use pulsed 193-nm argon fluoride ultraviolet lasers to remove submicron amounts of tissue are being investigated. Laser keratomileusis involves reshaping the anterior surface of the

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cornea. The laser can also be used to make linear excisions, as in standard radial keratotomy, but wound healing remains a problem.

Altogether, about 15 different corneal surgical techniques to correct refractive errors are being investigated, and the field remains one of the most active and intriguing in ophthalmology.

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Current Uses of Collagen Shields

COLLAGEN shields are biodegradable contact lens-shaped films made of porcine or bovine scleral collagen. After placement on the eye, naturally occurring enzymes in the tear film cause the shields to dissolve over a 24- to 72-hour period, depending in part on the degree of collagen cross-linking induced at the time of manufacture. Their use as a clinical tool in ophthalmology is now widely accepted.

Recent studies have proved the collagen shield to be an excellent vehicle for drug delivery to the eye. Dexamethasone, gentamicin, tobramycin, and vancomycin hydrochloride all have been shown to have equal or greater concentrations in the cornea, aqueous, and iris when a soaked collagen shield was placed on the eye as when hourly drops or subconjunctival injections were used. The shields also have been shown to enhance corneal epithelialization postoperatively and after corneal abrasions.

In light of this recent research, some ophthalmologists are now routinely using collagen shields soaked in antibiotics and corticosteroids postoperatively as a replacement for subconjunctival injections in cataract, corneal, and anterior segment procedures. Follow-up has shown these eyes to be less inflamed in the immediate postoperative period with less discomfort. Other potential applications are using the shield in treating bacterial corneal ulcers, enhancing the healing of persistent epithelial defects or neurotrophic corneal ulcers, and possibly as an adjunct to dry eye therapy.

The collagen shields' capability of drug delivery, protection, lubrication, and accelerating epithelialization makes them particularly useful in ophthalmic surgical procedures and should prove to be a valuable therapeutic tool.

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Botulinum Toxin for the Treatment of Blepharospasm and Strabismus

IN his pioneering work, Scott showed that an injection of small quantities of a purified reconstituted solution of botulinus toxin type A (Oculinum) into an extraocular muscle will cause a dose-related but temporary paralysis of the muscle. The drug is intended as a medical alternative to the surgical procedures currently used to treat blepharospasm and certain strabismus conditions. A chemically denervated muscle will cause a change in the position of the eye. With prolonged administration, some degree of contracture of the antagonist muscle is thought to occur, presumably resulting in a lasting alteration of ocular alignment.

The Food and Drug Administration (FDA) has recently granted premarket approval to botulinus toxin for treating blepharospasm and strabismus in patients at least 12 years old. Oculinum, which is a lyophilized form of purified botulinus toxin type A, blocks neuromuscular conduction. When injected in therapeutic doses, it produces a local denervation muscle contractions associated with blepharospasm. Botulinus toxin type A is administered by a subcutaneous injection at specific sites around the eye. Its beneficial effects last an average of $12^1/_2$ weeks. Injections may need to be repeated, and this should not be viewed as a failure.

In one clinical study, botulinus toxin type A was administered to 27 patients with essential blepharospasm, 26 of whom had been treated unsuccessfully with benztropine mesylate, clonazepam, baclofen, or some combination of the three. Of the 27 patients, 25 reported improvement within 48 hours of the initial treatment. One patient's blepharospasm was later controlled with a higher dose. The other patient reported only mild improvement. In an open trial to test the effectiveness of the antitoxin in treating strabismus, 667 patients with strabismus were given one or more injections of the drug. Of the 667 patients, 55% had improved to an alignment of ten prism diopters or less when evaluated six months or more after injection. To date, 4,000 patients have received more than 7,000 injections to treat strabismus. Likewise, in the treatment of blepharospasm, more than 4,000 patients have received well over 7,000 treatments.

Although some practice with the technique is important, once the skill is acquired, it is a relatively safe office procedure for treating strabismus that requires only an injection of the drug into the extraocular muscle. Although successive treatments may be necessary, the success rate approaches that of standard strabismus surgical procedures.

At this time, the FDA has released botulinus toxin type A for treatment of strabismus in patients 12 years of age and older, excluding it for treatment of childhood strabismus and particularly for infantile esotropia. Currently, however, there are research protocols in effect for the treatment of congenital esotropia, and early reports indicate promising results.

Transient ptosis has been reported as a side effect in about a third of the patients, and some investigators have reported unexpected hypertropias at a rate of 15%. Other complications that have been reported are 9 cases of scleral perforation, none of which resulted in retinal detachments, and 15 cases of retrobulbar hemorrhage, again with no permanent disability resulting.

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Evaluating Functional Vision

VISION traditionally has been evaluated using a Snellen chart and notation. The chart presents black and white letters of different sizes that are scaled to quantify the resolution of the eye. Patients frequently complain that their vision deteriorates as they age and that they have trouble seeing to drive at night. The Snellen eye chart often reveals normal acuity in these persons. The standard eye chart was developed during the Civil War period before the invention of the electric light bulb or high-speed driving. Disorders such as cataracts, diabetes mellitus, and macular degeneration may not be evaluated properly with the existing eye chart. The term functional vision has been coined to describe what we need to test. This denotes the visual ability to perform under various lighting situations.

The Snellen system tests the resolution of our eyes with black letters on a white background. Most of our vision is achieved by detecting the differences between borders, however. The degree that a person can determine the subtlest change gives us an important measure of the quality of vision. This kind of testing is called contrast sensitivity. There are two clinical testing systems in use today. The first presents to the patient sine wave gratings in which either the frequency or the contrast can be changed. Each eye is independently shown a target of vertical gratings. The grayest resolvable grating represents the contrast sensitivity for that frequency. The gratings are then made narrower and the entire process is repeated. The second system is easier to administer and is clinically more available. A patient simply is shown different-sized letters that are grayed out until they can no longer be read. This system is easier to do clinically and relates contrast sensitivity to the standard Snellen notation.

Another important measure of functional vision is how well we see in situations of glare. It is possible to have normal acuity and contrast sensitivity and to be completely blinded in the presence of any strong extraneous light source. Frequently patients have complaints of headlights obscuring their night vision. Even during the day, strong front lighting can wash out their vision. New tests have been devised that challenge acuity and contrast sensitivity in the presence of a glare source.

As we age, acuity may remain in the 20/20 range but our contrast and glare capabilities diminish. Frequently by age 70, patients' contrast has so diminished that they have difficulty driving at night. In the dark, it is hard to see on poorly illuminated roads. Tests based on contrast sensitivity may be used in the future to assess a person's visual fitness for driving.

Cataracts are a disorder of aging that can be well evaluated with the above tests. Various government reimbursement programs now require certain visual standards before they will allow ocular operations. Hence, measuring contrast and glare in addition to standard Snellen acuity is a useful adjunct in further characterizing visual loss.

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Extended-Wear Soft Contact Lenses

ACCORDING to a recent Food and Drug Administration survey, nearly 20 million Americans wear contact lenses with most using soft lenses. Soft contact lenses can be used either on a daily-wear basis in which the lenses are removed and disinfected each day or on an extended-wear basis with the lenses worn overnight for a variable number of days. The most serious complication of contact lens use is bacterial corneal ulcers, which may result in corneal scarring and loss of vision requiring corneal transplantation.

Recent reports suggest that the risk of bacterial corneal ulcers is greater with the use of extended-wear than daily-wear soft contact lenses. A multicenter case-control study confirmed this observation and showed that users of extended-wear soft contact lenses who wore them overnight had a risk of bacterial corneal ulcers that was 10 to 15 times as great as that for users of daily-wear soft contact lenses.

Bacterial corneal ulcers in contact lens wearers probably require two conditions: the presence of pathogenic microorganisms that may be contaminating the eye or some aspect of the care system and a break in the corneal epithelium either from trauma or hypoxia caused by the contact lens. The use of an extended-wear soft contact lens may be associated with chronic corneal hypoxia that may disturb epithelial metabolism and result in epithelial defects through which pathogenic bacteria gain access to the corneal stroma.

Disposable soft contact lenses are extended-wear hydrogel contact lenses that are intended to be worn either six-nights-on, one-night-off and then discarded or on a daily basis and discarded every two weeks. Disposability is practical because these lenses are inexpensive.

Disposable soft contact lenses may have several advantages. First, they may reduce problems caused by noncompliance with good lens care because less lens cleaning or disinfection is required. Furthermore, the risks associated with aging lenses, such as cracks or other surface defects that might allow microbial penetration or deposits that might facilitate bacterial adherence, should be reduced. Other possible benefits include eliminating some of the allergic and toxic complications of contact lens care products. Despite all these advantages, the disposable lens has an oxygen transmissibility that is similar to other hydrogel contact lenses. In other words, this lens may be just as likely to cause chronic hypoxic stress to the cornea as other hydrogel lenses when used on an extended-wear basis. Although bacterial corneal ulcers have been associated with the use of disposable lenses, it is not known whether they are safer than other hydrogel lenses in this regard.

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Update on Retinopathy of Prematurity

RETINOPATHY of prematurity (ROP), previously known as retrolental fibroplasia, is a proliferative disorder of infant retinal blood vessels that can lead to blindness. While previously associated with the administration of oxygen in excess of need, the single most important factor that determines whether the condition develops under conditions of modern neonatal intensive care is the degree of an infant's prematurity. Although most cases of ROP regress spontaneously, infants with very low birth weights have a greatly increased incidence of ROP that is likely to be severe. With recent increased survival rates for infants weighing much less than 1,000 grams at birth, blindness due to ROP has become an international concern.

Retinopathy of prematurity now is classified according to an international system that allows clinical investigators to communicate better. Using that system, a multicenter clinical trial (Cyro-ROP) showed that cryotherapy administered for stage III + ROP approximately halved the rate of poor anatomic outcomes as defined by the study. In the Cryo-ROP study, only one eye of symmetrically affected infants was treated, and current recommendations generally continue this practice because of the unknown long-term fate of treated eyes.

The availability for the first time of effective treatment of retinopathy of prematurity mandates a screening program by an interested ophthalmologist in every neonatal unit that cares for premature infants. Because the most important factor determining whether ROP will develop is birth weight, a birth weight criterion rather than an oxygen criterion appears logical, and many institutions screen all infants with birth weights of less than 1,500 grams. Because infants are highly unlikely to reach the threshold for cryotherapy before 6 weeks of age, earlier screening examinations probably are neither necessary nor warranted.

Parents of infants discovered to have threshold ROP should be offered the opportunity to have at least one eye of their baby treated with cryotherapy. Informed consent should include the warning that cryotherapy reduces but does not eliminate the risk of severe visual loss and that a complete permanent loss of vision in one or both eyes is possible despite the best available management.

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AIDS and the Management of Cytomegalovirus Retinitis

CYTOMEGALOVIRUS (CMV) retinitis is by far the most common vision-threatening disorder seen in patients with the acquired immunodeficiency syndrome (AIDS). Before the introduction of specific antiviral therapy against cytomegalovirus, progressive retinitis developed in these patients, terminating in blindness due to destruction of the retina. Two clinical presentations of CMV retinitis may occur—peripheral and central. Peripheral cytomegalovirus retinitis is often asymptomatic. An astute patient may notice "floaters," which represent inflammatory cells in the vitreous cavity, and also a peripheral visual field defect. It is uncommon for patients to be aware of such symptoms, however. Flashing lights may also occur as traction is placed on the retina. Peripheral disease cannot be diagnosed with the direct ophthalmoscope; visualization of the peripheral retina is best with the head-mounted binocular indirect ophthalmoscope. This examination must be done through a dilated pupil. Central CMV retinitis affects the retina closer to the optic disc and macula. This can be diagnosed by an internist or primary care provider using the direct ophthalmoscope. Dilation of the pupil is also helpful in visualizing the posterior third of the retina. Patients often will describe a visual field loss as the retina close to the central vision is affected. Visual acuity loss may also occur, either through direct involvement of the fovea (the central retina) or owing to fluid associated with adjacent CMV retinitis. In such cases, immediate therapy is required to prevent a complete loss of vision.

Patients with either peripheral or central CMV retinitis typically have systemic infection elsewhere that may be subclinical. In such patients, buffy coat cultures are often positive, indicating the systemic importance of this disease. For the past several years, many groups have had experience with the new antiviral drug, ganciclovir. These groups have shown clearly that healing of retinitis occurs during therapy with this drug. In 1989, the Food and Drug Administration approved this agent for the treatment of cytomegalovirus retinitis. Intravenous infusion of this drug prevents enlargement of the lesions within a week, and over a period of three to four weeks healing and a resolution of retinal hemorrhage and edema occur. Several groups have shown, however, that if the drug is discontinued at any time, retinitis recurs. Physicians can be misled into thinking that the retinitis is healed because clinically it does look completely inactive. The drug is virostatic, however, and it almost invariably recurs. This is important to understand because discontinuing the drug will eventually lead to loss of vision. Daily maintenance therapy with ganciclovir is required for the life of these patients. The currently recommended dose is 5 mg per kg twice a day for 10 to 14 days—the induction dose—followed by a maintenance regimen of 5 mg per kg a day 7 days a week. Drug "holidays" and poor compliance may lead to a slowly progressive retinitis that can eventually destroy the central vision.

The care of patients with cytomegalovirus retinitis must be a joint effort between an infectious disease specialist or primary care provider experienced in administering toxic antiviral drugs and an ophthalmologist trained in indirect ophthalmoscopy and retinal disease. Wide-angle fundus photographs are essential to monitor the healing of the disease, to confirm a lack of progression, and to detect early reactivation. Typically photographs are taken at the time of diagnosis and some two to four weeks later as the retina heals. Subsequent photographs can be taken at each examination or when any change is noted clinically.

With such management, recent studies show that more than 75% of patients retain excellent central visual acuity for the duration of their lives. Unfortunately, bone marrow toxicity is a major problem in patients undergoing ganciclovir therapy and may make the concurrent use of zidovudine difficult. Other drugs including foscarnet are currently being evaluated by the Studies of the Ocular Complications of AIDS group in a randomized trial sponsored by the National Eye Institute. Centers are in New York, Baltimore, Miami, New Orleans, Chicago, Dallas, San Diego, Los Angeles, and San Francisco. Such studies will determine the best antiviral drugs for treating CMV retinitis. Other recent developments include the possible use of ganciclovir in an oral form; the narrow therapeutic ratio of this drug may make such therapy difficult. Several groups are currently evaluating the use of granulocyte-monocyte colony-stimulating factor as an adjunct to ganciclovir therapy. This recombinant cytokine may be useful in treating the neutropenia that is the common side effect of ganciclovir.

Retinal detachment is a devastating complication of CMV retinitis and often occurs in patients with healed retinitis who previously had good vision. This complication occurs in as many as 20% of patients treated for CMV retinitis, often in both eyes. Vitrectomy surgical techniques are now available that can repair these retinal detachments in most patients. The definitive procedure includes using silicone oil in many cases. The decision to do this surgical procedure will depend on the visual acuity in a patient's other eye and the potential lifespan of the patient.

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Current Recommendation for the Treatment of Diabetic Eye Disease

THE Early Treatment of Diabetic Retinopathy Study (ETDRS), a National Eye Institute-supported, multicenter, randomized clinical trial, has shown that photocoagulation therapy for diabetic macular edema substantially reduces the risk of loss of vision. Macular edema is a leading cause of vision loss in patients with diabetes mellitus and occurs in approximately 10% of the diabetic population. It results from fluid leakage from microaneurysms and defective retinal vessels with subsequent retinal thickening and hard exudate formation within the macula. Data from the ETDRS show that focal photocoagulation of "clinically significant" macular edema reduces the risk of vision loss by more than 50%. Laser treatment also increases the chance of visual improvement, decreases the frequency of persistent macular edema, and is not accompanied by any major adverse effects. Of note is that the benefits of treatment occur regardless of level of visual acuity at the time of treatment. As a result, even diabetic persons with normal vision may have macular edema that should be considered for photocoagulation therapy.

The ETDRS also investigated the question of optimal timing for panretinal photocoagulation therapy. The results of the study had shown that panretinal photocoagulation substantially reduced the risk of blindness resulting from the high-risk proliferative states of diabetic retinopathy. The ETDRS results confirm that panretinal photocoagulation therapy reduces the risk of severe vision loss. In addition, investigators found that the benefits of treatment occur whether such therapy is given "early" or deferred until high-risk proliferative retinopathy occurs.

Finally, aspirin treatment was studied to determine whether it was effective in altering the course of diabetic retinopathy. The ETDRS results showed that a dose of 650 mg a day did not prevent the development of high-risk proliferative retinopathy. In addition, aspirin therapy had no effect on vision and did not increase the risk of vitreous hemorrhage.

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Using Fluorouracil in Surgical Therapy for Glaucoma

INCREASED intraocular pressure is strongly correlated with the risk of glaucomatous optic nerve damage. Current glaucoma therapy involves lowering the pressure to a level that is compatible with preserving the integrity of the optic nerve. This level may vary from patient to patient. Factors such as family history, race, myopia, and diabetes mellitus play a role in increasing the risk of damage from elevated pressures. The efficacy of therapy is determined by careful monitoring of the optic nerve appearance and by repeated measurement of the field of vision. When progressive damage continues to occur despite maximum medical therapy, a glaucoma-filtering operation may become necessary to further lower the intraocular pressure.

In glaucoma-filtering operations, a drain site connecting the anterior chamber and the episcleral space is fashioned at the junction between the cornea and sclera. This drain, which is covered by an outer coat of conjunctiva, creates a pocket or bleb into which aqueous humor flows. By directing aqueous from the inner eye into a new tissue space, the drain effects a persistent lowering of the intraocular pressure.

The average success rate of glaucoma-filtering surgical procedures in previously unoperated eyes is 75% to 85%. Although often successful initially, with time a significant number of filters fail. This occurs as a result of the normal healing response. Fibroblast proliferation at the operative site can lead to scarring, closure, and functional failure of the filter. It is thought that pharmacologic modulation of this healing response, with suppression of scarring, could improve filtering bleb survival.

Recently investigators in a large, prospective, randomized multicenter study reported a substantial improvement in the results of glaucoma filtration surgical procedures with the postoperative use of fluorouracil. All patients enrolled in the study were at a high risk for failure, having either undergone previous filtering surgical procedures or cataract extraction. The fluorouracil was injected subconjunctivally for two weeks after the filtering operation; 73% of treated versus 50% of untreated patients had successful outcomes at one year. Complications were reported but thought to be at an acceptable level.

Although earlier pilot studies showed that adjunct fluorouracil was of possible benefit in patients with a poor prognosis, clinical use has not yet been widespread. This large, well-controlled study validates the use of this agent in defined high-risk patients undergoing glaucoma filtration procedures. Through inhibition of fibroblast proliferation and scarring in the region of the surgical drain site, this therapy allows for a greater chance of continued aqueous filtration and control of intraocular pressure.

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The Dilemma of Neonatal Ophthalmic Prophylaxis

THE most frequent cause of neonatal infectious conjunctivitis today is no longer gonorrhea but chlamydia. This sexually transmitted disease caused by Chalmydia trachomatis is increasing rapidly in incidence (at least 3% annually) and, in addition to conjunctivitis, can cause pneumonia in infants.

While many states require silver nitrate to be the sole prophylactic antimicrobial medication, in as many as 90% of infants the medication itself induces a toxic conjunctivitis producing redness, edema, and a watery or purulent discharge. This reaction can be confused with gonococcal conjunctivitis, the very disease this agent was used to prevent.

Some states, such as California, will permit an agent other than silver nitrate to be used if it is effective. Because of the toxic conjunctivitis associated with using silver nitrate and its assumed ineffectiveness against chlamydia, many hospitals began using topical erythromycin or tetracycline. Gonorrheal or chlamydial conjunctivitis has developed, however, despite the prophylactic use of these medications. In a large prospective study in Kenya comparing the use of silver nitrate with that of erythromycin, both agents were about equally effective against gonococci, Chlamydia trachomatis, and other forms of ophthalmia neonatorum. A larger prospective American study found that erythromycin and tetracycline ointments were just as effective for prophylaxis against gonococcal and chlamydial conjunctivitis as silver nitrate solution.

Another controversy involves the universal administration of the eyedrops. A recent study found that 80% of babies born of cesarean section within three hours of rupture of the membranes had conjunctivae that were sterile, whereas the rest bore a few cutaneous bacteria. Clearly these infants would not benefit by receiving ocular prophylaxis, as they are not exposed to the organisms of the birth canal. Infants born more than three hours after the membranes rupture may benefit from prophylaxis because they predominantly had a microaerophilic bacterial conjunctival flora similar to babies delivered vaginally.

The prevention of neonatal infectious conjunctivitis has not been totally achieved. Research needs to be conducted to better identify those newborns at risk who should receive prophylaxis and to develop better agents than those currently being used.

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A Report on the Activities of the New Haven County Medical Association Committee on Physician Health

WILLIAM B. LYONS, M.D., ANN W. HARNEY, AND GARY W. FREBERG

THE charge to this Committee is as follows:

> "The Committee on Physician Health shall receive and evaluate complaints and/or reports brought by the public or members regarding impairment of physicians practicing in New Haven County. They shall also educate members about their responsibilities in this area...."

The first Connecticut committee on physician health was established by the Hartford County Medical Association in the late 1970s and addressed the issue of physician impairment. The title of that body was the "Committee on the Impaired Physician," and it also was the first name given to the committee that was established by the New Haven County Medical Association in 1980. The name of the committee was changed to the "Committee on Physician Health" in the early 1980s, a title that was felt to be more appropriate.

Since then the Fairfield County Medical Association has established a similar committee, as did the Connecticut State Medical Society in May 1988 on behalf of the State's five other counties.

The New Haven County Medical Association's Committee on Physician Health, since its inception, has provided essential services to the people of New Haven County by identifying physicians who might be unable to practice medicine safely, and by working with such physicians to help them overcome their problem whenever rehabilitation seemed to be a realistic possibility. The committee, when it is appropriate, establishes a diagnosis and recommends treatment in conjunction with a defined program of rehabilitation.

The pertinent General Statutes of the State of Connecticut applicable to the functioning of this Committee include:

(1) Chapter 370, Section 20-13c through Section 20-13e which is concerned with the reporting and investigation of complaints against physicians by the Department of Health Services;

(2) Chapter 370, Section 20-8a through Section 20-9 which is concerned with Connecticut's Medical Examining Board and professional licenses;

(3) Chapter 675a, Section 38-19a, which addresses peer review.

New Haven County Medical Association's Committee on Physician Health is composed of 10 physicians whose medical specialities and hospital affiliations are representative of the county's medical community. Essential to the function of the committee is that the members be able and willing to give of their time, and that they possess the appropriate expertise: namely, the ability to discern whether a physician, and here I quote from the General Statutes of the State of Connecticut, "is or may (sic) be unable to practice medicine with reasonable skill or safety for any of the reasons listed in Section 20-13c."

When an oral complaint or referral is made to the committee, a request is made for it to be put into writing. Whether in writing or not, two members of the committee, or a staff person and a committee member, interview the person making the complaint and/or the referral. If the complainant is a women, one of the two representing the Committee on Physician Health will also be a woman.

Confidentiality begins at the onset of this process and is maintained throughout. A file on each referral is opened and referenced by number. Inquiries are made to all possible sources (associates, partners, office staff, other physicians, nurses, hospitals, clinics, family, friends, etc.). When the inquiry is complete, and if the data accumulated indicate that a problem might exist, the physician is inter-

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WILLIAM B. LYONS, M.D., Chairman, Committee on Physician Health, ANN W. HARNEY, Associate Executive Director, GARY W. FREBERG, Executive Director; all of the New Haven County Medical Association, Hamden.

viewed by two committee members and a committee staff person, as indicated. The physician is informed of the reasons for this confidential visit, of the allegations that have been presented to the committee, and of the data that might support this allegation. A request is made for an observed urine specimen immediately after the interview. This request is made in almost all inquiries. The specimen, identified by number only, is sent to an analytical laboratory to determine if any controlled substance is currently being used. The findings from the interview and any related information are reviewed by committee members and a decision is made as to a proper course of action. Two reports are required to be made to the Department of Health Services. A "Stage I Report" containing the allegation must be forwarded within 30 days of the receipt of the initial complaint. The identity of the physician is not required in the initial report unless reason exists to believe that immediate intervention is necessary. A "Stage II Report" is required within 45 days of the receipt of the initial complaint, and this report identifies the physician.

The Stage II Report will recommend one of several courses: (1) that the case be closed because the complaint is spurious, (2) that further inquiry is required, or (3) that the physician be permitted to participate in a program of rehabilitation under the aegis of the Committee on Physician Health. In the event the committee determines that a problem does exist, but the physician refuses to cooperate, the Department of Health Services is requested to handle the case. When the committee believes that the situation is an emergency, and that an immediate threat to patient safety and welfare exists, the Department of Health Services is notified immediately.

Physicians who agree to participate in the program are notified that they will need to sign a Consent Agreement with the Department of Health Services. The Consent Agreement contains the terms of the physician's rehabilitation program. Such agreements are designed on a case-by-case basis. The Consent Agreements, which are monitored by the committee, generally last from two to five years. The management of unlicensed physicians, such as residents, is the same as that for licensed physicians, except that reporting to the Department of Health Services is not required. The committee also provides this service to fellows, medical students, and physicians who are not members of organized medicine.

Though the preponderance of complaints has involved the abuse of alcohol and other substances, the committee also addresses complaints or referrals concerning emotional disorders and physical or neurological impairment. In these cases, the committee implements appropriate consultations and appropriate testing where indicated.

As in many other situations, the committee has observed that there is not much new under the sun. The first documented definition of alcoholism in this country is attributed to Dr. Benjamin Rush (circa 1786). He stated that alcoholism was a disease whose characteristic was a loss of control over drinking behavior and whose cure was abstinence. This definition is certainly as applicable today as it was then, except that we have added many other substances to the category of drugs of abuse. In 1957 the American Medical Association first defined alcoholism as a disease, and 30 years later, in 1987, the American Medical Association added the abuse of other controlled substances as diseases of addiction.

Since 1 June 1985, when the committee became fully active, 37 allegations have been addressed. During the first year of the committee's activities, the largest percentage of referrals came from patients; since that first year, referrals have come primarily from the medical community, including the physicians themselves who seek treatment. To make the program activities more readily available, committees on physician health were encouraged and established in three hospitals within New Haven County. Unfortunately, this potentially valuable resource for diagnosing and treating candidates for recovery has not yet evolved to the extent we had hoped, though we are continuing our efforts to involve all the hospitals in the county. Of the physicians who are participating in the program, the majority are doing well, and we have received numerous expressions of their appreciation for the support extended in their treatment and recovery.

Of significant benefit has been the committee's ability to identify spurious allegations made by individuals against physicians. These have been indicated as such to the Department of Health Services and those cases have been closed without publicity or the need for legal action.

A statement in the February edition of *Federation Bulletin,* the monthly publication of the Federation of State Medical Boards, is indicative of a more enlightened environment. John H. Morton, M.D., associate editor, wrote: "Today the approach to impairment is in terms of rehabilitation rather than punishment whenever possible. There are two basic premises inherent in this approach: (1) The physician must recognize that he or she has a problem and be willing to participate actively in a long term recovery process. (2) It must be possible to carry out the rehabilitation without risk to the patient."

It has been our experience that Connecticut's Department of Health Services also appears to subscribe to this approach. The Department, to date, has concurred with our recommendations in the cases addressed. It is significant to note that one case was referred to us by the Department of Health Services. We believe this is the first referral in Connecticut to a committee on physician health.

This, of course, is the ideal—that the work of committees on physician health is recognized by the Department of Health Services, resulting in a cooperative effort to protect patient safety while allowing the physician committed to rehabilitation the opportunity to do so.

The following is a summary of the cases addressed by the committee between 1 June 1985 and 1 September 1990.

Allegations

(Some cases contained more than one allegation)

Substance abuse: 10

Inappropriate professional conduct: 8

Alcohol abuse: 7

Emotional disorders: 5

Illegal or excessive script writing: 4

Neurologic diseases: 2

Criminal activity: 2

Incompetency: 1

Status

Cases closed in agreement with Department of Health Services (spurious complaints): 13

Cases referred to Department of Health Services for further investigation: 9

Physicians entered into consent agreement: 7

Cases referred to and under the auspices of other Committees on Physician Health: 4

Cases currently under investigation: 2

Physician in rehabilitation program only: 1

Cases closed upon fulfillment of terms of consent agreement: 1

Source of Complaint

Self-referral: 12

Patient: 9

Other physician: 6

Anonymous: 2

Other medical society: 2

Hospital: 2

Committee on Physician Health: 1

Department of Health Services: 1

Public: 1

Physician's family: 1

The members of New Haven County Medical Association's Committee on Physician Health are: Robert F. Buckman, M.D., Dorothy W. Brockway, M.D., Craig W. Czarsty, M.D., Joseph P. Dineen, M.D., Gerald H. Flamm, M.D., Josephine M. Fuhrmann, M.D., Mark L. Kraus, M.D., Charles E. Leach, Jr., M.D., and John P. Nowicki, M.D.. Robert L. Arnstein, M.D. and Jerome K. Freedman, M.D., are consultants to the Committee.

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An M.D.-J.D.'s Response to the Medical Malpractice Crisis

SAUL BOYARSKY, M.D., J.D.

We have a malpractice crisis in the United States that concerns us all and represents the tip of the iceberg of social change.

The causes of this malpractice crisis include among others: litigious patients, unrealistic public expectations of medical outcomes, weakening of the doctor-patient trust, the depersonalization resulting from team and technologic medicine, publicity regarding bad medicine and monster doctors, and negligent errors in the medical practice.

Law suits can result from disputes fuelled by three factors: (a) a medical grievance or resolved misunderstanding with a patient, (b) an underlying pattern of professional behavior that can be characterized as an "accident waiting to happen," and (c) an inciting spark, the medical injury, poor result, or accident.

From the point of view of malpractice prevention, it helps to know about lawyers, the law, and the legal system. It is far more useful, however, to know about ourselves, our medical habits, and our patients. As individual physicians, we can do a great deal to avoid litigation and actually practice better medicine by (a) minimizing patient misunderstandings and (b) examining and overcoming our own poor habits.

I shall address myself to a collection of professional attitudes and habits that in part distinguish the seldom-sued doctor from the oft-sued doctor. These ten guidelines, collected from many sources, answer the frequently posed question on how to stay out of medical-legal trouble.

The ten precepts, guidelines, or commandments are:

1. Listen well to patients, their families, staff, and colleagues.
2. Keep impeccable medical records.
3. Practice risk management and consult promptly in regard to troublesome incidents.
4. Understand and practice informed consent.
5. Continue your medical education.
6. Join the bioethics movement.
7. Get involved as an advocate for medical causes and health care.
8. Understand and use sound business practices.
9. Be compassionate.
10. Be counted among those willing to censure unsound medical practices and practitioners.

Let us now examine each of these precepts.

1. Listening is a fine art. Most of us are better at talking than we are at listening. Excellent rapport, however, is the first line of defense against the misunderstandings that predispose to lawsuits. Those sued the least have the best rapport with their patients. Good listening is fundamental to lawsuit prevention; it lays the basis for trust and a solid doctor-patient relationship.

Physicians should learn to listen for: (a) what was said; (b) what was not said; (c) what the patient wanted to say but could not; and (d) what the patient really meant to say.

Patients under stress may not hear or understand. If a patient is under stress, the physician must make sure that a responsible member of the family group hears and understands the message. Recording such conservations on the chart can be valid and inexpensive defensive medicine.

Good patient rapport requires that the physician's staff also be sensitive to patient's questions and concerns. The secretary or nurse may be the first to alert the physician to misunderstandings and forestall a breakdown in rapport and thus prevent a lawsuit.

SAUL BOYARSKY, M.D., J.D., is a retired professor of urologic surgery at Washington University School of Medicine, where he was also head of the Law and Medicine program. He holds a law degree and was admitted to the Missouri Bar in 1983.

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It is especially important for a physician to maintain rapport after things go wrong. Keep listening and express your instinctive sympathy. Do not abandon the patient by avoidance. Do not hesitate to apologize. Regret can be voiced without confessing to a legal misdeed. An apology, offered promptly, often reduces the tension and tendency to litigation. An apology offered late can be interpreted as an admission of fault or guilt.

2. Impeccable medical records are the sine qua non of good practice. Be a good doctor, and let your records reflect it!

Record each essential element of the complete workup, the negative findings, the alternative differential diagnoses, the rationale for choosing the therapeutic option, the substance of the informed consent.

A cynical saying in the law is that if you didn't record it, you didn't do it.

Medical records can become legal documents. Hence, in a legal proceeding, any erasure, alteration, illegibility, abbreviation, adverse remark, or unfortunate wording can be turned against a physician. The legally appropriate way to made a correction is by adding information in context and continuity, dating and initialing it. Do no black out or delete any existing entries and do not destroy a record. Legally, altering the record shifts the burden of proof of negligence, so that the physician will be presumed guilty rather than innocent until proven otherwise.

3. The most vulnerable area of practice is in the hospital. This is where 80 percent of all lawsuits against doctors originate. Hospitals must be made safe so that public confidence in them is restored.

Hospital functions must be reviewed from the top to the bottom. Risk management is the management system designed to meet this challenge. This requires new staff attitudes, new informational data bases, and a system of monitoring and feedback.

If something goes wrong, the physician should seek advice from more experienced colleagues and report it promptly to the hospital risk manager, the chief of staff, possibly even the public relations officer, the insurance company, and the lawyer.

Every adverse incident should be described factually and honestly in the chart, with appropriate diagrams, and prudent impounding of any devices involved. Documentation should be comtemporaneous and dated so that questions arising a year or two later will have been anticipated and answered. This is good defensive medical practice and medical education, and improves quality control in the hospital.

4. More than two decades after the enunciation of the legal doctrine of informed consent, and its statutory adoption in most states, this concept is still largely misunderstood. This is because its basic philosophy is still not grasped.

The basic philosophy of informed consent states that it is the patient who is in charge and that it is the doctor who is the servant. Today's physician has the obligation to educate the patient, but the patient has the right to choose or refuse the treatment. Medical paternalism is no longer an accepted doctrine.

How much do patients need to know in order to be able to make choices adequately? The patient should know everything needed to decide whether or not to undergo therapy, surgery, a diagnostic procedure, or to refuse a diagnostic procedure. The patient must know the diagnosis, each therapeutic option, the foreseeable outcomes, risks, and benefits of all the options, including the option of doing nothing.

Informed consent can only be practiced as an ongoing process between physician and patient. It is not just a signed document. The patient must have a good idea of what he is going to experience and enter into it of his own free will and choice. This puts the patient into the legal position of assuming part of the risk and making the final decisions.

5. The physician must avoid professional obsolescence. Lawsuits have been filed on the grounds of "failure to keep abreast." With so many continuing opportunites currently available, no physician has an excuse for not keeping up with current medical advances.

6. Join and support your bioethics committee. It is better to hear a nurse's anger or angst, a family member's disagreement, or a colleague's misgivings prospectively in an ethical forum than retrospectively in a legal forum. No one wants to play God, nor do we want to shun all responsibility. The life-and-death decisions, the right to die, the "no code" orders, and the right to terminate therapy are frequent questions that stretch our competence. A bioethical deliberation should include the patient and/or his representative, the family, community representative, religious representative, the doctor, lawyer, and hospital administrator. In hospitals, the bioethical committee should function as a consultation service.

Over time, we can expect some of the bioethical guidelines to be translated into legal standards and statutes by state legislatures. After a decade of public discussion involving doctors, lawyers, ministers, and the laity, the right to die statute was passed in Missouri in 1985. Now physicians in Missouri can write "do not resuscitate" orders without fear of criminal prosecution.

7. Today, physicians must get involved in society's debates. Our best stance is to be a health and patient advocate. As individual physicians we can complain about lawyers, insurance rates, regulations, or injustice,

but we remain powerless to change the situation until we unite. When physicians do exert leadership, they have proven to be surprisingly powerful in bringing about changes. We physicians have entered the public and political arena in too few numbers and too late. Many mechanisms for change exist. The American Medical Association, specialty societies, and local medical societies all have legislative action committees. More of us must get involved in coalitions to debate the positions with which we disagree. We must get behind those movements that improve health care access or meet other health needs of patients and the public.

8. Economics and business have been thrust upon the medical profession. Rather than being tempted by seductive joint ventures or employment contracts, today's young physician must look instead to sound marketing and business practices. The physician can learn from the business community how to achieve success by hard work, going where one is needed, being first with the best product, and striving for consumer satisfaction. The physician must be available, affable, and able, or, in another mnemonic, accessible, affordable, accountable, and acceptable.

This is not to say that there are not unsolved quandaries in the business of medicine. Which advertising is tasteless? Which contracts put the physician into a bind of conflicting interests? Which regulations and HMO contracts interfere with professional freedom of decision? Other business considerations include antitrust and hospital issues, Medicare fraud, and many other activities that require legal guidance. For these matters, the physician would be well advised to consult his personal lawyer.

9. Be compassionate and merciful. This needs little or no discussion, just repetition. A brusque or uncaring response to competing demands for attention may hurt a vulnerable patient. Conversely, compassion may heal a lot of hurt and lead to patient forgiveness.

10. The 1980 American Medical Association Code of Ethics directs physicians to "expose those physicians deficient in character, competence or honesty."

We physicians have often blinded ourselves to the need to police our profession. We can no longer blame others for not cleaning our house. Physicians must take the initiative. Health economists and lawyers have told us that a major factor in the current professional liability crisis is the perceived breach of faith between doctors and patients in the failure of the medical profession to police itself. Among other steps, licensing boards must not let the physician's property rights to practice intimidate them when the public health is jeopardized by low quality, obsolescent, fraudulent, venal, or unnecessarily risky medical practices. Due process rights must be given their legal respect, but not used as a delaying tactic.

With experience, guidance, and forensic dialogue, each specialty could promulgate standards of care for its expert witnesses.

Anesthesiologists in Boston and St. Louis have set specific standards for minimal patient monitoring during anesthesia as a means of eliminating their most frequently sued upon errors.[1,2] By writing their own practice standards, these anesthesiologists have set legal standards for practice that have also served for courtroom use. This action preempted the vagaries of the layman, the lawyer, and the unqualified expert. Coincidentally, their professional liability rates have started to fall.

We physicians need to balance the loyalty we owe colleagues with the loyalty we owe to patients. No longer can we see no evil, hear no evil, and speak no evil. The fiduciary relationship to our patients demands that we be honest and forthright. If called upon in the appropriate case, a physician must be willing to stand up and be counted among those who will expose and publicly oppose poor medical practice. When we physicians clearly set personal interest aside and dispel some public fears and misperceptions, the public's love affair and high esteem of physicians will be restored.

Conclusion

These ten precepts are separate stations on the way to evolving a more adaptive attitude to the practice climate of the 1990s.

Health law constitutes the channeled efforts of the people toward achieving improved health care for all. The public, through government, has taken over the control of medicine; it has even renamed it "health care." Our duty and challenge is to respond constructively. These ten precepts summarize the major lessons drawn from the medical-legal mistakes of the past twenty years. They might even serve as a modern "guide for the perplexed,"[3] to help us retain basic principles through the current health care storm and to adapt to our changing world.

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ARMY RESERVE MEDICAL PROFILE NO.9

Dr. Holwick outside of hospital where she practices as a civilian traumatologist.

Dr. Holwick in operating room at Letterman Army Medical Center.

JANN L. HOLWICK, M.D.

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OUTSTANDING ACHIEVEMENTS Borden Freshman Prize; Alpha Lambda Delta; Phi Beta Kappa Phi Kappa Phi; Bovard Award; ALD Award; American Institute of Chemists Medal Award; Summa Cum Lau University of California; Alpha Omega Alpha.

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Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include:
- Hypersensitivity reactions have been reported in about 1.5% of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of **serum-sickness-like** reactions have been reported with the use of Ceclor. These are characterized by findings of erythema multiforme, rashes, and other skin manifestations accompanied by arthritis/arthralgia, with or without fever, and differ from classic serum sickness in that there is infrequently associated lymphadenopathy and proteinuria, no circulating immune complexes, and no evidence to date of sequelae of the reaction. While further investigation is ongoing, **serum-sickness-like** reactions appear to be due to hypersensitivity and more often occur during or following a second (or subsequent) course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults with an overall occurrence ranging from 1 in 200 (0.5%) in one focused trial to 2 in 8,346 (0.024%) in overall clinical trials (with an incidence in children in clinical trials of 0.055%) to 1 in 38,000 (0.003%) in spontaneous event reports. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy; occasionally these reactions have resulted in hospitalization, usually of short duration (median hospitalization = two to three days, based on postmarketing surveillance studies). In those requiring hospitalization, the symptoms have ranged from mild to severe at the time of admission with more of the severe reactions occurring in children. Antihistamines and glucocorticoids appear to enhance resolution of the signs and symptoms. No serious sequelae have been reported.
- Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis have been reported rarely. Anaphylaxis may be more common in patients with a history of penicillin allergy.
- Gastrointestinal (mostly diarrhea): 2.5%
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1% and, rarely, thrombocytopenia and reversible interstitial nephritis.

Abnormalities in laboratory results of uncertain etiology.
- Slight elevations in hepatic enzymes.
- Transient lymphocytosis, leukopenia, and, rarely, hemolytic anemia and reversible neutropenia.
- Rare reports of increased prothrombin time with or without clinical bleeding in patients receiving Ceclor and Coumadin concomitantly.
- Abnormal urinalysis; elevations in BUN or serum creatinine.
- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly).

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285.

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CONSENSUS CONFERENCE

Conference on Intravenous Immunoglobulin

NATIONAL INSTITUTES OF HEALTH

Introduction

IMMUNOGLOBULINS are proteins produced by cells of the B lymphocyte lineage that are the major effector molecules of the humoral immune system. Immunoglobulin molecules are antibodies that react with specific antigens, although in many circumstances, the specificity of a given immunoglobulin antibody is unknown. Immunoglobulin preparations from human blood were first used in clinical medicine in 1952 to treat immune deficiency conditions. At that time, the only available preparations required intramuscular administration. In the past decade, several immunoglobulin preparations for intravenous administration have become available. Although initially used for immune deficiency states, intravenous immunoglobulin (IVIG) has also been utilized as a prophylactic and therapeutic reagent in a variety of other conditions. The use of IVIG has undergone tremendous growth in the past several years. This rapid growth in use is the result of improvements in the preparations of IVIG, which have led to reduced morbidity and reports of its benefits in a number of unexpected circumstances. IVIG has been used in such diverse diseases as primary immunodeficiencies, pediatric AIDS, infections in low birthweight infants, bone marrow transplantation, chronic lymphocytic leukemia, idiopathic thrombocytopenic purpura, Kawasaki syndrome, and demyelinating polyneuropathies. However, important questions regarding its use still remain.

To assess the usefulness of IVIG in diseases where substantive data existed, the National Institute of Allergy and Infectious Diseases and the Office of Medical Applications of Research of the National Institutes of Health convened a Consensus Development Conference on Intravenous Immunoglobulin: Prevention and Treatment of Disease on 21-23 May 1990. Cosponsors were the National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Child Health and Human Development, National Institute of Neurological Disorders and Stroke, and the Food and Drug Administration. In the various disease states in which IVIG has been used, the following questions were considered:

- What are the data to support the efficacy of IVIG in these circumstances?
- What are the appropriate dosage and treatment schedules?
- Are all IVIG preparations equally efficacious?
- What are the risks involved in the use of IVIG?
- What are the mechanisms of action?
- What are the directions for future research?

After a day and a half of presentations by experts in the field and discussion by the audience, a consensus panel drawn from specialists and generalists from the medical profession and related scientific disciplines, clinical investigators, and public representatives considered the evidence and came to the following conclusions:

1. What Are the Data to Support the Efficacy of IVIG in these Circumstances?

Primary Immunodeficiencies

The beneficial effects of intramuscular (IM) injection of immune globulin (IG) in the prophylactic treatment of patients with primary immunodeficiency syndromes have been well established. Early studies based on small sample sizes have indicated that almost any desired blood level of IgG can be obtained by use of intravenous immunoglobulin (IVIG) and that infection rates are reduced by use of IVIG as compared with IM IG. IVIG has been shown to ameliorate chronic sinopulmonary disease that developed in patients on long-term IM IG. There is a suggestion that chronic enterovirus meningoencephalitis in patients with X-linked agammaglobulinemia may be less frequent in those receiving prophylactic IVIG as

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NIH Consensus Development Conferences are convened to evaluate available scientific information and to resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

NIH Consensus Statements are prepared by a nonadvocacy, nonfederal panel of experts based on (1) presentations by investigators working in areas relevant to the consensus questions during a 1½-day public session; (2) questions and statements from consensus attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and the morning of the third day. This statement is an independent report of the panel and is not a policy statement of the NIH or the federal government.

From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, MD.

compared with historical data in which IM IG was used. Hence, IVIG has become the current standard in clinical practice for replacement therapy of patients with primary immunodeficiencies (eg, X-linked agammaglobulinemia and common variable immunodeficiency and immunoglobulin subclass deficiency in which deficiencies of antibody production to common pathogens can be demonstrated). Studies have shown that maintenance of a trough level of 500 mg/dl is beneficial. Dose ranges of 200-800 mg/kg/mo have been shown to be effective, but dose or frequency of infusions must be tailored to the individual patient, because half life of infused IVIG varies widely.

Pediatric AIDS

Because AIDS is an acquired immunodeficiency, it is reasonable to consider the use of IVIG therapy in pediatric patients with HIV infection, given the success of IVIG in primary immunodeficiencies. To date, small, uncontrolled studies have suggested the efficacy of IVIG in pediatric AIDS by decreasing the morbidity from common bacterial pathogens, as well as measles, but no controlled studies have been completed. Currently, the National Institutes of Health (NIH) is sponsoring two large, controlled trials of IVIG with and without zidovudine (AZT) in HIV-infected children. A definitive assessment of the efficacy of IVIG in pediatric HIV infection awaits the results of these trials.

Infections in Low Birthweight Infants

a. Prevention of infection in low birthweight infants

Premature infants have insufficient placental transfer of maternal IgG and have been demonstrated to have low levels of serum IgG. Hence, it is reasonable to consider IVIG prophylaxis in premature infants. Some pilot studies indicated a lower rate of severe infection in IVIG-treated low birthweight infants compared with placebo-treated patients. In a recently completed randomized, double-blind, placebo-controlled trial involving a large number of infants with birthweights of 500-1,500 g, it was noted that mortality was not significantly reduced among IVIG recipients. However, the number of infections was significantly reduced among IVIG recipients. It should be noted that there was some evidence that beneficial effect may vary by birthweight category, and significantly more placebo patients were small for gestational age. Information about long-term results (greater than 56 days) is not available from this trial. Moreover, preliminary analysis of other trials indicates no significant difference in infection rates between IVIG recipients and placebo recipients. However, differences in study design make direct comparison of the various trials difficult. Further information will become available as a result of the ongoing trial sponsored by the NICHD Neonatal Research Network. At this time, IVIG cannot be recommended as standard prophylaxis of low birthweight infants.

b. Treatment of presumed neonatal infection

To date, small trials using primarily historical controls have yielded mixed results. Questions remain concerning dose, schedule, and patient selection. Variability in preparations and lots creates a number of difficulties in predicting results of treatment for specific organisms. There is a potential role for directed preparations containing specific antibodies. Furthermore, studies in neonatal animals have shown that in some situations survival is less with high concentrations of IVIG plus antibiotic compared with antibiotic alone. The routine use of IVIG as adjuvant therapy of neonatal infections cannot be recommended at the present time.

Bone Marrow Transplantation

In a large study of bone marrow transplant recipients, reduced rates of septicemia and local infection were noted for IVIG-treated patients (500 mg/kg weekly) compared with untreated controls. Several studies have shown a decreased rate of acute graft versus host disease (GVHD) in patients receiving IVIG, 500 milligrams to 1 gram per kilogram weekly. Results of limited trials suggest that in pediatric bone marrow recipients, reduction in infection and death but not GVHD has been associated with IVIG administration.

It has been noted that IVIG decreases the incidence of interstitial (presumably CMV) pneumonia but is ineffective in preventing CMV infections. IVIG plus ganciclovir is beneficial in treating CMV pneumonia in patients who are not ventilator dependent.

Chronic Lymphocytic Leukemia

A study in 10 centers in which 57 patients with CLL were followed for one year of observation has been completed. The incidence of major and moderate bacterial infections was significantly reduced in hypogammaglobulinemic CLL patients who received IVIG. The number of trivial infections was unchanged by intravenous immunoglobulin. Maintenance of serum IgG levels > 640 mg/dl tended to correlate with fewer infections, especially serious bacterial infections. The data support the conclusion that IVIG may be useful to prevent serious infections in patients with CLL with hypogammaglobulinemia.

Idiopathic Thrombocytopenic Purpura

Among children with ITP, the use of IVIG has been documented to increase platelet counts. This treatment is utilized in the rare pediatric patient with potentially life-threatening bleeding (eg, 400 mg/kg/d x2-5 or 1 g/kg/d x1 or 2). A number of therapeutic options are available for managing the child with newly diagnosed ITP who does not have serious hemorrhage: IVIG, corticosteroids, or close observation without therapy. IVIG has been used in chronic ITP to postpone the requirement for a splenectomy. There is no firm evidence of curative effects in either acute or chronic ITP. Responses appear to be similar with different manufacturers' products licensed for this purpose.

In adult patients with ITP, IVIG, at the doses indicated above, has also been used for the rapid correction of life-threatening thrombocytopenia, with or without corticosteroids. Administration every 10 to 21 days is usually required to maintain adequate platelet counts. Other indications include administration to steroid-refractory patients preoperatively. In addition, IVIG may be employed at the same dosage in patients who cannot use corticosteroids and in patients with immunodeficiency including those with HIV-associated thrombocytopenia. Although IVIG administration before scheduled splenectomy is effective, cost/benefit relationships are unclear because of the low incidence of complications during this procedure, even with extremely low platelet counts.

Kawasaki Syndrome

Studies of IVIG in Kawasaki syndrome using 400 mg/kg daily for four days indicate a prompt anti-inflammatory response in the acute phase and a significant decrease in the formation of coronary aneurysms compared with low/moderate aspirin administration regimens. More recently, a dosage schedule of 2 g/kg as a single administration has been shown to be at least as effective as the four-dose schedule. Complications of the larger single-dose administration were few. A smaller study using 1 g/kg as a single dose also seemed to suggest similar efficacy to the four-dose regimen.

IVIG and aspirin administration has become a standard treatment for Kawasaki syndrome. The panel agrees that on the basis of available studies, IVIG administered as a single dose of 2 g/kg is effective therapy for patients who fulfill the diagnostic criteria for Kawasaki syndrome. Treatment of patients recognized after the tenth day of the disease has not been studied systematically.

The advantages of treating patients with Kawasaki syndrome with IVIG as early as possible must be balanced against the probability that children with other inflammatory diseases will also be treated inadvertently. There is no evidence that this latter group of children will be benefitted.

Chronic Inflammatory Demyelinating Polyneuropathies

Several small studies have shown positive responses to IVIG in the majority of treated patients. Treatment needs to be periodically repeated to prevent relapse. When considered in comparison with customary treatments, IVIG may be easier to use and to be associated with fewer complications than repeated therapeutic plasma exchange and long-term glucocorticoids, respectively.

Guillain-Barré Syndrome

In a preliminary analysis of a large, randomized multicenter trial of IVIG compared with therapeutic plasma exchange, there is an indication of improved functional recovery for patients receiving IVIG. Definitive conclusions regarding the efficacy of IVIG in Guillain-Barré syndrome will need to await the final analysis of this study and other confirmatory studies.

Intractable Seizure Disorders

A number of uncontrolled studies and anecdotal reports have indicated benefit of IVIG administration in children with intractable seizures. The absence of randomized, double-blind studies does not allow specific recommendation to be made regarding such treatment. The panel emphasizes the need for controlled human studies in this area.

2. What Are the Appropriate Dosage and Treatment Schedules?

Effective doses of IVIG have been demonstrated in primary immunodeficiencies, ITP, and Kawasaki syndrome. Whether alterations in amount, frequency, or duration of administration will improve efficacy is not known. Specific details of dosage regimens are discussed in detail in the response to question one.

3. What Are the Risks Involved in the Use of IVIG?

The incidence of adverse events associated with the administration of IVIG is reported by the manufacturers to be in the range of 1 to 15%, usually less than 5%. Most of these reactions are mild and self-limited. Severe reactions occur very infrequently and usually do not contraindicate further IVIG therapy. Neither HIV nor hepatitis B infection has been transmitted to recipients of products currently licensed in the United States. The various IVIGs are manufactured from large numbers of donors whose plasma has been tested and found to be negative for hepatitis B surface antigen and HIV antibody.

A number of adverse events have been recognized. These include the following:

- Pyrogenic reactions marked by high fever and systemic symptoms.
- Minor systemic reactions with headache, myalgia, fever, chills, lightheadedness, nausea and/or vomiting.
- Vasomotor and/or cardiovascular manifestations, marked by changes in blood pressure and tachycardia. These may be related to occasional reports of shortness of breath and chest tightness.
- Hypersensitivity and anaphylactic reactions.

Risk factors. Patients with primary antibody deficiency syndromes may be at increased risk for reactions. Anaphylactic reactions induced by anti-IgA can occur in individuals who have a total absence of circulating IgA and antibodies to IgA. These are extremely rare in panhypogammaglobulinemic individuals and potentially more frequent in patients with subclass deficiencies. Frequency of reactions may be correlated with volume and/or rate of infusion. Seriously ill patients with compromised cardiac function may be at increased risk of vasomotor or cardiac complications manifested by elevated blood pressure and/ or cardiac failure.

Prevention and management. Adverse reactions often can be alleviated by reducing the rate or the volume of infusion. For patients with repeated severe reactions unresponsive to these measures, hydrocortisone, 1-2 mg/kg, intravenously, can be given 30 minutes before IVIG infusion. In those rare instances when reactions related to anti-IgA antibodies have occurred, use of IgA-depleted preparations will reduce the likelihood of further reactions. Avoidance of anaphylactic reactions may require the use of material completely devoid of IgA. Because the combination of the absence of IgA and the presence of anti-IgA antibodies is infrequent and reactions are rare, screening for IgA-deficiency is not routinely recommended for potential recipients of IVIG.

As with any biologic or pharmacological product, the potential for new or previously unrecognized adverse events should be anticipated. With IVIG these include the following:

- Transmission of blood-borne pathogens, such as the newly identified hepatitis C virus.
- Immunosuppression—for example, administration of IVIG has been associated with transient effects on immune response that do not appear to have clinical significance. However, with increased dosage of IVIG or new products for the treatment of specific infections, the possibility of adverse outcomes from immunosuppression should be considered.

After nearly a decade of experience, the safety of IVIG has been established. For any potential recipient, the small risk of adverse reactions must be weighed against the likelihood of significant benefit. For those patients who require repeated courses of IVIG, such as those with a primary humoral immunodeficiency, home infusion by the patient or a family member after adequate training has been effectively utilized and is cost-effective.

4. What Are the Mechanisms of Action?

At the present time, we assume that all effects of IVIG are related to the quantity and quality of IgG in the product. Various mechanisms may be important in the different therapeutic uses of IVIG, including (1) replacement therapy for primary and secondary immunodeficiencies, (2) specific passive immunotherapy, and (3) management of specific inflammatory and/or immunologic disorders.

Efficacy of IVIG infusions in primary immunodeficiency diseases is probably related to replacement of antibodies to environmental pathogens. Despite variations in the titer of specific antibodies, all licensed preparations are apparently efficacious in the treatment of these diseases. In addition, pooled antibodies may have physiologic activities other than pathogen recognition that may contribute to the beneficial effects of replacement therapy.

The effectiveness and the mechanism of action of IVIG in secondary immunodeficiencies such as indolent lymphomas is presumed to be similar to that in primary immunodeficiencies. In these diseases, a reasonable correlation between rates of systemic infection and concentrations of serum immunoglobulins supports this presumption. The benefit of prophylactic replacement of IgG in very low birthweight infants is not established. Attempts to replace antibodies may be rational in this situation. However, it is possible that administration of immunoglobulin from large donor pools could adversely affect the development of the infant's immune system, as there is substantial evidence in mice that anti-idiotypic antibodies may profoundly affect immune responsiveness. For conditions such as bone marrow transplantation and pediatric HIV infection, the complexity of immunologic abnormalities will make determination of mechanisms extremely difficult.

IVIG is also being used for specific passive immunotherapy. In these instances, the titers of specific antibodies are of paramount importance. Moreover, consideration must be given to the possibility that large amounts of apparently irrelevant antibodies may block receptors on the surface of phagocytes and thus interfere with effective disposal of microbial pathogens.

In the treatment of ITP, there may be multiple mechanisms of IVIG action. The platelet count increase occurring within several days of the initiation of therapy appears to be caused by diminished sequestration of autoantibody-sensitized platelets. This may be caused by interference with Fc receptors on the cells of the monocyte-macrophage system. A similar mechanism may operate in other autoimmune and alloimmune cytopenias. Sustained responses to IVIG may represent spontaneous remissions or may be related to an immunosuppressive effect of IVIG.

There are several possible mechanisms by which the infusion of large concentrations of immunoglobulins may have an immunosuppressive effect. The presence of IgG dimers in immunoglobulin preparations, a result of pooling samples from a large number of individual donors, likely represents the occurrence of idiotype-anti-idiotype complexes. There is evidence that anti-idiotype antibodies in IVIG react with epitopes on the autoantibodies in patients with thyroiditis or spontaneous factor VIII inhibitors. Alterations of T cell subsets and of in vitro B cell function, both spontaneous and mitogen driven, have been reported in patients treated with IVIG. It is unknown if these observation are related to a mechanism of therapeutic effect.

A striking anti-inflammatory effect of IVIG has been observed. This phenomenon is most apparent in Kawasaki syndrome, where reductions in fever, neutrophil counts, and acute phase reactants regularly occur within a day or so of initiation of treatment. This effect is not unique to Kawasaki syndrome but has been seen in other inflammatory disorders. The mechanisms are unknown but may be distinct from those that mediate immunosuppression. One possible mechanism demonstrated in experimental animals is the inhibition of complement-dependent tissue damage caused by binding of IVIG to active C3 fragments.

There is a great need for an understanding of the mechanisms of IVIG in the various conditions in which it is used. A variety of mechanisms have been suggested but none proven. Mechanistic hypotheses such as the provision of anti-idiotype antibodies, Fc receptor blockade, and alteration of reticuloendothelial cell system function should be rigorously tested. Utilization of appropriate animal models would provide an efficient way to test these hypotheses.

5. Are All IVIG Preparations Equally Efficacious?

Seven IVIG preparations have been licensed in the United States: all seven for use in primary immunodeficiencies, five for idiopathic thrombocytopenia, and one for chronic lymphocytic leukemia. For these disease groups, the limited comparative data available reveal no differences in efficacy among the licensed preparations. For the other uses of IVIG, there is insufficient information to choose one product over another or to know whether each has comparable activity. Given the large number of conditions for which IVIG may have potential value, the prescribing physician should be aware of the demonstrated efficacy of each IVIG preparation to treat a specific disorder.

The products and their quality are under the control of commercial firms who must meet general regulatory guidelines of the Center for Biologics Evaluation and Research/FDA. These include tests for sterility, pyrogenicity, purity, and safety. It is required also to measure antibody levels against polio, measles, hepatitis B, and diphtheria. At the present time, there is no requirement to identify hepatitis C virus in IVIG preparations. Epidemiologic data support the quality and safety of current products. However, guidelines and monitoring methods must be developed as information about transmission of hepatitis C virus and other infectious diseases becomes better defined. Consideration should be given to screening donors for hepatitis C.

Confidence in the capacity of a given preparation to accomplish the desired end result would be enhanced if a more rigorous procedure were established for using IVIG to prevent or treat infections caused by specific microorganisms. The availability of antibody titers to a wider range of pathogens would permit a more rational basis for the choice of a specific product in situations where immunotherapy is directed to a restricted number of infectious agents. Because the factor essential for the effectiveness of IVIG in a number of disorders, such as ITP and Kawasaki syndrome, is unknown, it is not possible to predict efficacy of a given preparation of IVIG for any of these disease processes.

6. What Are the Directions for Future Research?

- The effects of IVIG in the various disease states can probably be accounted for by the presence of one or more specific antibodies. These may be directed against microbial pathogens or their toxins, common idiotypes, cellular components, receptors, or regulatory proteins. The need for massive doses of IVIG to achieve therapeutic effects suggests that many of these antibodies are present at very small concentrations in immunoglobulin pools. One of the major directions of future research therefore should be to identify and isolate these particular antibodies or prepare supplementary monoclonal antibodies so that more specific therapeutic interventions can be designed.
- There is a great need for an understanding of the mechanisms of action of IVIG in the various conditions in which it is employed. Without knowledge of specific mechanisms, progress in this area will be slow. This should be a major focus of future efforts.
- Appropriate objective outcome measures, including long-term outcome measures, should be established that can be applied in clinical trials. Cost-effectiveness and objective measures of quality of life should be included in this analysis. Without such outcome measures, results of additional clinical trials will be difficult to interpret.
- Controlled clinical trials in pediatric intractable recurrent seizures, chronic inflammatory demyelinating polyneuropathies, and Guillain-Barré syndrome are warranted in the United States.

In addition, consideration should be given to clinical trials in areas where compelling biologic reasons or experimental data suggest potential efficacy. There is no justification for clinical trials in areas without strong biologic rationales.

- Serious neonatal infections continue to be a major problem. Development of appropriate hyperimmune preparations of IVIG should be undertaken for this purpose.
- Comparative efficacy of various preparations of IVIG should be established, if possible.
- Surveillance for long-term positive and adverse effects should be carried out.

Conclusions

In answer to the question, "What are the data to support the efficacy of IVIG in various clinical circumstances?" the consensus panel concludes the following:

- IVIG is a safe and effective means of replacement therapy in patients with primary humoral immunodeficiency syndromes in which deficiencies of antibody production to common pathogens can be demonstrated. The ideal dosage of IVIG has not been established, although the monthly administration of 200-800 mg/kg appears to be adequate to maintain trough Ig levels at approximately 500 mg/dl in most patients.
- The usefulness of IVIG in pediatric AIDS has not been documented. Results are not yet available from two ongoing NIH-supported multicenter placebo-controlled double-blind trials being carried out to evaluate this issue in more detail.
- The use of IVIG in the prevention of late onset infections in preterm neonates has a rational basis. However, the data indicate that this is of no value in neonates of birthweight of more than 1,500 g. In neonates under 1,500 g, the results are conflicting. Thus, the currently available data do not support the routine use of IVIG in this group either. Although there may be an impact of IVIG on the rate of bacterial infections in this group and the length of hospitalization, there is no effect on mortality. The use of IVIG as adjuvant therapy in neonates with infections is not supported by the current data. Additional clinical trials, especially involving the use of hyperimmune preparations, would be useful to delineate this issue.
- In immunosuppressed bone marrow transplant recipients, IVIG is useful to treat interstitial (CMV) pneumonia, in combination with ganciclovir. IVIG may be protective against gram-negative septicemia and development of local infections in these patients. In addition, IVIG may suppress GVHD in some patient groups.
- In hypogammaglobulinemia associated with chronic lymphocytic leukemia, IVIG can decrease the number of infections significantly. Although it has no effect on mortality, there is a decrease in the number of days per year spent in a hospital or convalescing.
- The comparative efficacy of IVIG versus corticosteroids or other approaches has not been clearly delineated in either adults or children with ITP. IVIG is useful in the treatment of pediatric acute ITP where it usually increases the platelet count rapidly. In adult ITP, it can also induce increases in the platelets. In adults, it is most useful in special circumstances requiring acute increases in the platelet count, such as immediately before surgery.
- IVIG in conjunction with aspirin is the current standard of care for children during the first 10 days of Kawasaki syndrome to prevent the development of coronary aneurysms.
- IVIG shows some promise in the treatment of chronic inflammatory demyelinating polyneuropathies, and Guillain-Barré syndrome, and therefore additional clinical trials are warranted.
- There is the preliminary suggestion that IVIG might be useful in certain childhood intractable seizure disorders. Therefore, clinical trials are warranted.

In response to the question, "What are the appropriate dosage and treatment schedules?" the consensus panel concludes that in most circumstances this has not been established. For primary and secondary immunodeficiencies, ITP, and Kawasaki syndrome, effective regimens have been developed, but there is no evidence about whether these schedules are optimal.

In response to the question, "Are all IVIG preparations equally efficacious?" the consensus panel concludes that the preparations are efficacious for the indications for which each has been licensed. Although it is possible that they can be used for other conditions interchangeably, the comparability of the various preparations of IVIG for these purposes has not been documented.

In response to the question, "What are the risks involved in the use of IVIG?" the consensus panel concludes that they are minimal. However, appropriate means to monitor IVIG for contamination with potential pathogens should be developed.

In response to the question, "What are the mechanisms of action of IVIG?" the panel concludes that in most circumstances present hypotheses are speculative and not proven.

In response to the question, "What are the directions of future research?" the panel concludes information concerning mechanism of action is critically needed. Deriving information concerning mechanisms of action or other potential uses of IVIG from clinical experiments and trials is costly and inefficient. Without knowledge concerning anticipated objective physiologic end points, trials to establish effective therapeutic regimens are empiric and new initiatives largely exercises in serendipity.

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Speakers were:

Carol J. Baker, M.D., "Intravenous Immunoglobulin in Low Birthweight Infants: Prevention"

Karyl S. Barron, M.D., "Treatment of Kawasaki's Syndrome: A Comparison of Two Dosage Regimens of Intravenous Immune Globulin"

James B. Bussel, M.D., "Outline of the Use of IVIG in Immune Cytopenias"

Helen Chapel, M.D., "Intravenous Immunoglobulin Therapy Prevents Bacterial Infection in Patients With Secondary Hypogammaglobulinema Due to Low-Grade B Cell Tumors"

Charlotte Cunningham-Rundles, M.D., Ph.D., "Intravenous Immunoglobulin: Development as a Therapy and Unresolved Issues"

Av Fanaroff, M.D., "Preterm Infants: Intravenous Immunoglobulin to Prevent Nosocomial Infection"

Ralph D. Feigin, M.D., "Kawasaki's Syndrome: An Overview"

Gerald W. Fischer, M.D., "Use of Intravenous Immunoglobulin During the Treatment of Infection in Low Birthweight Infants"

Erwin W. Gelfand, M.D., "Dosing Regimens for Replacement Therapy in Primary/Secondary Antibody Deficiency"

William J. Harrington, M.D., "Idiopathic Thrombocytopenic Purpura"

Harry R. Hill, M.D., "The Role of IVIG in the Treatment of Bacterial Infection in Low Birthweight Infants"

Winston G. Ho, M.D., "The Role of Intravenous Immunoglobulin in Bone Marrow Transplantation"

Paul Imbach, M.D., "Intravenous Immunoglobulin Treatment of Immune Thrombocytopenic Purpura (ITP) in Children"

Roger J. Kurlander, M.D., "The Use of Intravenous Gamma Globulin in Treating Adult ITP"

Jane W. Newburger, M.D., M.P.H., "Use of IVIG in Kawasaki Syndrome"

Hans D. Ochs, M.D., "Intravenous Immunoglobulin (IVIG) in Primary Immunodeficiencies"

James M. Oleske, M.D., "Historical Approach of the Use of IVIG in Pediatric AIDS"

Fred S. Rosen, M.D., "Overview of Issues"

William T. Shearer, M.D., Ph.D., "Review of Clinical Trials in the Literature"

Keith M. Sullivan, M.D., "Immunomodulatory and Antimicrobial Efficacy of Intravenous Immunoglobulin in Bone Marrow Transplant Recipients"

Donald L. Tankersley, A.B., M.S., "Intravenous Immunoglobulins: Past, Present, and Future"

Alberto G. Ugazio, M.D., "Childhood Recurrent Seizures"

Frans G.A. van der Meché, M.D., Ph.D., "The Effect of High-Dose Immunoglobulins in Acute and Chronic Inflammatory Demyelinating Polyneuropathy"

Anne D. Willoughby, M.D., M.P.H., "NICHD Clinical Trial of IVIG in HIV Infection in Children"

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Societal Effects and Other Factors Affecting Health Care for the Elderly

AMA COUNCIL ON SCIENTIFIC AFFAIRS

TODAY'S elderly Americans comprise a generation that has brought about, and lived through, an extraordinary spectrum of change in our nation's society. During the first half of the 20th century, they witnessed changes that were previously unimaginable. From a peaceful, isolationist, horse-and-buggy society at the beginning of the century, the United States became an industrial society of awesome scientific and technical skills, the inventor of atomic power, and the most powerful and influential nation in the world.

For today's elderly who helped bring about this transformation, the transition involved turbulent economic and societal change. In less than 50 years, the people endured the sacrifice and austerity of World War I, the economic boom and social changes of the 1920s, the prolonged hardships of the Great Depression in the 1930s, and the upheaval and sacrifice of all-out national mobilization during World War II. Some men had barely finished fighting for their country and settling down to civilian careers when they were recalled to fight again in the Korean War in 1950.

Perhaps it was in some ways good that Americans had become accustomed to cataclysmic change, because the second half of the 20th century brought technological and social changes that were as profound as the economic and geopolitical changes of the prior half century. Society was again totally changed as our nation went through the "Cold War," the space age, the civil rights movement, the sexual revolution, the women's liberation movement, the Viet Nam War, the peace movement, Watergate, and the computer age.

The United States has emerged vastly improved in terms of wealth, material luxuries, and economic stability. Young men no longer face military conscription, and many persons feel that the threat of war seems more distant than at any time in the past 50 years.

While the elderly have witnessed these profound changes during their lifetimes, they have also enjoyed better health and increased longevity. The successful treatment of previously fatal conditions by modern medicine has led to prolonged lives and the longer duration of many chronic conditions.[1]

Medical care has made giant leaps forward. Infectious diseases are being increasingly brought under control. Life expectancy has skyrocketed upward, and so has the elder population. The elderly (age 65 and older) tend to have more chronic diseases and consume a disproportionate share of health care expenditures.[2] The 21st century may greet us with an epidemic of chronic illness and associated disabling conditions.[3]

In an effort to improve health care for the elderly, physicians and gerontologists may ask: What does our fast-paced, rapidly-changing society mean for our nation's elderly? Have they been left behind in our rapidly-changing society? Or are they better off now than they were a generation ago?

In caring for the elderly, legislators (who provide much of the funding), health professionals (who provide much of the care), and family members (who provide care and funding) must have an appreciation of how much our current prosperity was built upon decades of sacrifice by today's older population. Many of the decisions about entitlements for the elderly in future years will be made by "baby boomers" who have never known an economic depression or had their lives disrupted by war or military conscription. Hopefully, today's elderly will be treated fairly and cared for with understanding and love by a society of their children and grandchildren who know something about what they have been through and what they have done to bring out the prosperity now enjoyed in the United States.

A Demographic Upheaval: The Aging of America

The designation of the elderly as 65 years old and older is attributed to Kaiser Wilhelm in the late 1800s. Demo-

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This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of September 1989.

Presented by: William C. Scott, M.D., Chairman graphers have used that figure since then.[4] In the past 100 years, the total United States population multiplied 5 times, but the over-65 population multiplied 15 times. Every day, about 3,400 elderly Americans die and 5,000 Americans celebrate their 65th birthday creating an increase in the elderly population of 1,600 per day.[5] The population of the United States that is 65 and older has grown remarkably since 1900 (See Table 1):[4]

Table 1

Year	*U.S. Population Over 65 (millions)*
1900	3
1960	12
1985	28
2030	58 estimated

Some estimates predict that by the year 2030 the elderly population will be more than 65 million.[6] We know that the rate of growth will take a sharp further upturn around 2011 when the "baby boomers" born between 1946 and 1964 begin to turn 65.

Even more dramatic is the rate of growth of the U.S. population 85 and older, which is the most rapidly growing part of our population (see Table 2).[4]

Table 2

Year	*U.S. Population Over 85 (millions)*
1900	0.15
1985	2.7
2000	5.6
2030	11.0 estimated

The elderly consume a disproportionately large amount of the nation's health care. Thirty three percent of health care expenditures are made for persons 65 and older, although they comprise only 12% of the total population. By the year 2020, the elderly will consume nearly half of the nation's health care services.[7]

Effects of American Society on the Elderly

Advances in medical science have helped older members of our society a great deal. Society has done much to improve the quality of life for older Americans. Some of this is immediately apparent (such as the enactment of Social Security, Medicare and Medicaid, establishing the National Institute on Aging, and so forth), but much has been done through local organizations, including thousands of volunteer efforts.

The United States is a wealthy nation that has carried out extensive research in geriatrics and gerontology in an effort to solve not only major problems among the elderly, such as Alzheimer's disease, but also the smaller every-day problems such as "caregiver burn-out." The amount of research on projects great and small in geriatrics and gerontology done each year in this country is indeed remarkable.

Nevertheless, we are in many respects a youth-oriented society, and the status of the elderly has become relatively diminished in certain ways. Nancy Osgood has observed that the relative status of the elderly tends to decrease in societies that are more urbanized, modernized, and technologically developed.[8] She argues that the elderly in this country are often viewed as "useless, dependent, nonproductive— a burden to be borne by younger members of society." They are "over the hill" and "put out to pasture." She further observes:

> The elderly in this country are advised to buy cremes to cover up "those ugly age spot and wrinkles," to join health and figure spas and try all sorts of diets to "keep that youthful figure." Hair dyes to "get rid of that ugly gray," dentures and tooth polish to "recapture that youthful smile," and tonics and pills to "feel young and look young again" are also available. If all of these remedies fail to transform an old face and figure into a young one, the multibillion dollar cosmetic business in the United States surely can perform the miracle.

Seiden has addressed the relatively high suicide rate in the elderly, particularly among elderly white males, in the United States.[9] He states, "As cultures become less traditional, when age is no longer seen as a pathway to wisdom, when extended families fly to the wind, when people are considered interchangeable parts, when progress is highly valued, the suicide rates of the elderly will rise."

The elderly tend to be devalued and hold less power in technologically advanced societies.[10] Commenting about this observation, Rosow[11] states that the relative position of the aged in any society is determined by six institutional factors: (1) ownership of property and control over the opportunities of the young, (2) command of strategic knowledge and skills, (3) strong religiosity and sacred traditions, (4) strong kinship and extended family bonds, (5) a low-productivity economy, and (6) high mutual dependence and reciprocal aid among members. He maintains that in American society, the elderly suffer a loss of status in all of these dimensions.

There is certainly no single answer to the question, how does society affect the elderly in America today? The effects are mixed—some good and some bad for the elderly. Those who care for aging patients may profit by understanding these various effects.

The Battle to Control Medicare Costs

There has been a significant increase in the political power of the elderly during the past decade, due in part to the growth of the American Association of Retired Persons (AARP). A major voice for the elderly, AARP represents more than one fifth of the nation's voters. A person must be over 50 to join, and forty-eight percent of Americans over 50 are members. Every day, AARP gains 8000 new members.[12] In spite of its formidable power, AARP projects an image of an organization that uses its influence with restraint.

AARP is working to increase long-term health care benefits and other entitlements for older citizens. The organization's newsletters and other publications, including *Modern Maturity*, reach 17.9 million households. The AARP has taken an active role in matters concerning Medicare and the availability and quality of medical care for the elderly.

The political power of the elderly will be put to a test in the coming months and years in the battle to provide the best possible medical care to increasing numbers of the elderly in spite of mounting efforts to control Medicare expenditures. The Congress and the White House are becoming increasingly concerned with the Federal deficit, and they see the control of Medicare spending as a necessary step to limit the rising costs of health care for the elderly.

Limiting the increases in Medicare costs is a difficult task, because continuous improvements in medical science make health care increasingly expensive. When this is coupled with the fact that the elderly population continues to grow (at a rate of about 1,600 persons every day, as previously noted), the task is doubly difficult.

In 1983, Medicare introduced the Prospective Payment System (PPS) as a means to control hospital costs through the use of Diagnosis-Related Groups (DRGs). Hospital reimbursement rates were set prospectively according to diagnosis. These specify the amount that will be paid by Medicare and puts pressure on the physician and the hospital to discharge the patient promptly. Once DRGs were in place, patients were leaving the hospital and going home "quicker and sicker." Sometimes this led to medical complications and rehospitalization. This has been documented with regard to suboptimal rehabilitation of patients with hip fractures.[13] Rehospitalization during the 2-week period following original hospitalization was increased after the PPS and DRGs were initiated.[14]

In effect, DRGs have controlled costs by shortening inpatient care (reducing inappropriately high levels of care) and encouraging more outpatient care. However, physicians and their elderly patients are concerned that DRGs are causing a decrease in the quality of care. AARP and other organizations testified before Congress in 1986 about this concern. The result was provisions in the Omnibus Budget Reconciliation Act (OBRA) of 1986 which mandated that existing Peer Review Organizations review the quality of care in hospitals. The goal was to ensure that the government's cost-containment efforts did not lead to poor quality medical care.

In the years immediately following the introduction of DRGs, there was a precipitous decline in the use of inpatient hospital services.[15] By 1987, rates of hospital admissions declined more slowly, and the length of stay per admission began to rise for certain medical problems. Further analysis is needed to evaluate whether quality of care and access to care for Medicare beneficiaries has been affected.

In 1989, efforts are continuing by the government to try to hold down the cost of health care in the face of a steadily increasing elderly population and continously better and more sophisticated medical technologies. The recent Report by the Physician Payment Reimbursement Commission to Congress proposes three cost-containment measures to help contain Medicare Part B physician costs: 1) expenditure targets (ETs), 2) practice guidelines, and 3) the resource-based relative value scale (RBRVS). Most practicing physicians and the AMA agree that practice guidelines and the RBRVS will be helpful because they allow identification of appropriate and inappropriate care. However, many people are concerned that ETs will, in effect, ration care without discrimination as to whether it is appropriate or inappropriate care. The Bush administration supports the concept of ETs.

One proposed version of ETs would set a "target" that would permit Medicare spending on physician services to grow 9.6% in 1990 rather than 10% to 12%, which had been planned earlier according to forecasted need. Leaders of organized medicine are understandably concerned.[16] They point out that this would constitute a form of rationing of medical care for the elderly.

Financial Status of the Elderly

In recent years, the elderly in general have become better off economically. Their financial security has been enhanced particularly by improvements in Social Security benefits and by Medicare and Medicaid which were enacted in the mid-1960s. During the late 1960s and early 1970s, a decrease in poverty among the elderly was seen.[17,18]

Nonetheless, the percentage of elderly persons living below the poverty line has remained relatively unchanged in the past several years, and elderly persons living alone suffer poverty rates that are five times higher than elderly couples. Poverty among those living alone afflicts primarily widowed women and its highest among minorities.[19] Forty-one percent of elderly women are poor or near-poor (near-poor indicates an income of 100-149% poverty level), in contrast to 17% of elderly men. This difference reflects women's lower wages during working years, inadequacies in social security coverage, and increased risk of financial devastation from widowhood and longevity.

The cost of medical care is a substantial burden for the elderly and for public programs. Public spending on health care for the elderly is 3.5 times greater than for persons under 65.[20] About 40% of the costs of Medicare and Medicaid are incurred during the last 3 months of life.[21] Overall health care expenditures for the elderly were $119.9 billion in 1984.[22]

In spite of the fact that public programs pay for a huge amount of elderly health care, older individuals continue to pay increasing amounts out-of-pocket. These expenditures by the elderly have risen from $966 per year in 1980 to $1,526 in 1984 and are projected to be $2,583 in 1990.[22] This concern over costs on the part of the elderly is further illustrated by the heated discussions regarding the supplemental premium imposed to finance the Medicare catastrophic illness insurance program.

Special Problems in Elder Health Care

Numerous reports have documented a widespread indifference or negative attitude among the health professions towards specialization in care of the elderly.[23,24] It is discouraging to note that there is relatively low interest in geriatrics among medical students.[23,25] Despite the recent growth of interest in geriatrics, most physicians are not adequately trained in the care of the elderly.[26] Many excellent training programs in geriatrics are now available, but physician interest continues to be limited.

Medical school curricula are gradually beginning to integrate geriatrics and gerontology into their programs in response to a growing demand for physicians trained in geriatrics. When such training is begun early in medical education, the impact on student attitudes may be greater.[27] Myths about the elderly may be dispelled and empathy may be encouraged through simulation exercises which put the medical student into the role of the elderly patient. Such exercises increase the students' awareness and understanding of psychosocial and physical experiences of old age.[28,29,30]

Finally, the American family has changed a great deal over the past 40 years. The isolation of the elderly and the separation of generations today is an unfortunate modern phenomenon. Portnow and Houtmann[31] urge that people seriously consider caring for an elderly spouse, parent or relative at home when this is feasible. This arrangement provides satisfaction and lasting rewards for the caregiver. For the patient, the quality of care is usually much better.

Medicare now pays for many types of home care, and this has made possible the rapid growth of the home care industry in the past two decades. There have been innovations in "high tech" home care, including intravenous administration of medications and many other diagnostic, therapeutic and rehabilitative procedures. Training in home care needs to be included in the curricula of medical schools and nursing schools to prepare physicians and nurses to appropriately utilize these services.

Psychosocial Issues in "Successful Aging"

Psychosocial factors may have a profound influence on elderly patients. Two very important factors are autonomy (or control) and social support.[32]

The importance of autonomy to health and to quality of life is well documented.[33] Loss of autonomy has adverse effects on emotional states, subjective well-being, performance, and physiologic indicators. Older persons commonly encounter loss of autonomy for a variety of reasons — physical impairment, reduced economic status, residential moves from their home to a combined or institutional living arrangement, and so forth.

When undesireable events occur and the individual has no control, the stress is greatest and the outcome poorest. When the individual has control, or partial control, the stress is lessened and the outcome better. These positive effects of maximizing the amount of individual autonomy have been demonstrated in controlled nursing home studies.[34] Health care personnel should therefore try to encourage autonomy whenever possible among elderly persons.

A patient's social network of family, friends and others also has a positive effect on mortality and well-being. Berkman[35] studied patients in Alameda County and developed a social network index that included marital status, social contact with family and friends, church group membership, and other factors. Over a 9-year period, mortality was found to be lower in people with a higher social network index. A study in Tecumseh (Michigan) reported similar findings over a 10-year period.[36] Furthermore, intervention studies involving supportive behaviors by health care personnel have shown that such support tends to hasten recovery and to improve compliance.[37]

The common problem of "caregiver burnout" is one that physicians should constantly keep in mind. The majority of care given to the elderly is provided by family members. It is not uncommon for a spouse or child of a patient to become physically and emotionally exhausted from the task of providing care. Physicians must be aware of this potential problem and keep communications open to the patient, caregivers, nurses, social workers and others. Caregivers should be advised about the availability of in-home services, day care, and respite care that can improve quality of care and ease their burden in caring for elderly loved ones.[38]

Ethical and Legal Issues

Decision-making for incompetent patients and the right to die

As our society has become more technically advanced, medicine has developed techniques to prolong life, resuscitate patients, and sustain vital functions by artificial means. Thirty years ago, families tended to rely on the counsel of their family physician and their pastor, priest, or rabbi. Ethical standards are now influenced more strongly by laypersons, the media, and patient advocacy groups. Our society has become consumer oriented and more litigious, and medicine has become more regulated by government and third party payers.

Many elderly patients who are terminally ill can be kept alive for weeks or months by artificial means. The patient's pain and discomfort can be severe and prolonged, even with the most conscientious medical care. Family members may be upset and uncertain about what to do. In cases where the patient has irreversible brain damage, artificial life support systems may keep the comatose patient alive for months.

Ethical dilemmas can be avoided when the patient writes advance directives. In a "living will," the patient may give directions about health care, to be followed in the event that he or she has a terminal illness or is incapacitated and cannot communicate.

Usually, a living will directs that if death is imminent, the fatal illness should be allowed to take its natural course without high-tech life support systems being used. Medical care should, of course, provide comfort and dignity to the patient.

Requirements for such documents— whether they must be notarized, the number of witnesses required— vary from state to state. Patients should inquire about these requirements and consult an attorney if necessary. The individual should then ensure that close family members and/or close friends (especially the person designated to have power of attorney) and the physician(s) have copies of this document. When a patient is hospitalized or institutionalized, the institution should also have a copy.

The individual and the designated agent(s) should discuss as many aspects of health care as possible that might require attention.[39] This should include discussions about prolongation of life, nutrition and hydration of the terminally ill patient, as well as other forms of life-sustaining equipment. It is important to discuss how the patient feels about placement in a nursing home or hospice, and about "do not resuscitate" (DNR) orders.

The physician's role in such matters has been addressed in a statement by the AMA Council on Ethical and Judicial Affairs, entitled *Withholding or Withdrawing Life-Prolonging Medical Treatment*. They have stated that if a patient has specified that he or she does not want artificial life support used during a terminal illness, it is not unethical for the physician not to use, or to terminate the use of, artificial life support equipment, providing there is medical certainty that the illness is terminal.

The person who has been designated to have power of attorney will have discussed these matters with the patient in the past, and will have the power to act for the patient in having the advance directives carried out. Physicians should encourage patients who are 65 or older, or who are seriously ill, to write advance directives if they are able to do so.

A recent report points out that while living wills are strongly endorsed in principle, they are rarely used in clinical practice because they are vague and difficult to apply.[40] The authors of this report propose the use of a new document, the Medical Directive, which is a more extensive and more specific type of living will and also provides for the designation of a proxy (durable power of attorney). It allows the individual to give advance directives on four different scenerios where the individual is either in coma or had brain damage. This gives valuable insights about the patient's wishes. The authors believe that the Medical Directive would prevent most of the drawbacks of living wills. They state, "Linguistic vagueness would be limited; interpretation would be well guided by stated patient views; and applicability would be extended and clarified. Proxy decisions would be available when no preferred sources were possible and would be aided by the Medical Directive."

Rationing of health care

Since the enactment of Medicare/Medicaid, the cost of medical care has risen enormously. The development of new medical technologies has also contributed to increasing costs. It has been suggested that expenditures for health care have exceeded reasonable boundaries, and that further increases in the nation's health care budget should be limited.[41] Since the elderly are consuming an increasingly large percentage of health care costs, one method that has been proposed to limit health costs is to limit government funding for elderly health care. This, in effect, would constitute rationing of medical care.

Physicians today are caught in transition between a society that advocates the unlimited use of medical care and one that advocates use of "only necessary medical care." In a sense, these are the philosophies of overtreatment versus undertreatment. Of course, the AMA believes that all appropriate care is necessary. However, during the 1980's, third party payers have attempted to contain medical care costs and influence the thinking of physicians about how much care is necessary. Mechanisms such as DRGs shift the incentives toward undertreatment.[42]

Rationing of care according to age may be an effort to allocate care according to the patient's worth to society. Since the majority of elderly persons are retired, they are assumed to be less productive. Expensive medical technologies are better spent, by this reasoning, on younger persons who can contribute more to society, and expensive procedures such as dialysis and organ transplants should not be covered by Medicare for the elderly. This age-based rationing does not call for value judgments. It could be applied equally across all social classes without discrimination.

This dilemma is discussed by L.R. Churchill.[43] He summarizes several points of view pertaining to the rationing of health care and maintains that many aspects of our medical care system are unjust. He concludes that "any morally justifiable age-rationing scheme will have to be lodged in a more just overall health care system."

From a somewhat different point of view, Christine Cassel has reviewed the subject of medical care.[42] The physician wants to be, and should be, she argues, an advocate for patients and does not want to be a gatekeeper. However, the physician will have to continue to play a key role in allocation of health care decisions (rationing). For this role to be an ethical one, Cassel specifies four criteria that should be met: (1) there must be universal access to a basic minimum level of care; (2) physician's levels of income must not be directly related to treatment choices; (3) there must be a closed financial system within which meaningful trade-offs can be made; and (4) there must be an ethically acceptable framework for decision-making.

The AMA Council on Ethical and Judicial Affairs recently reviewed the subject of rationing of medical care.[44] The Council observed that limiting access to health care on the basis of chronological age alone is a form of rationing that is closely tied to the concept of social worth. Since most of the elderly are not in the work force, they do not directly benefit society to the extent that younger persons do. However, such generalizations do not take into account the fact that the elderly are a very heterogenous group. While the majority of the elderly are retired, many of them are extremely productive. Indeed, many of our outstanding leaders, statesmen, scientists, scholars, philosophers, judges, writers, religious leaders, artists, and physicians are elderly.

Therefore, the Council asserts that the allocation of medical care according to an individual's perceived utility or relative worth to society based on chronological age is not appropriate. Furthermore, allocating medical care according to relative worth to society violates fundamental norms of distributive justice. The Council rejects the use of chronological age of patients as a criterion for allocating scarce health care resources.

An adequate discussion of all major ethical and legal issues affecting health care of the elderly is beyond the scope of this report. Among the most important of these issues is the crisis in professional liability, which has been one of the most troubling problems that physicians have faced in the past two decades.

Health Promotion for the Elderly

Rowe and Kahn[45] have written a provocative article, Human Aging: Usual and Successful. They emphasize that many of the "usual" manifestations of aging— impairment of glucose tolerance, osteoporosis, decreased cognitive and sensory functions, cardiovascular/respiratory disease— are influenced by external factors that can be controlled.

Fries[46] and others emphasize that most chronic disease can be effectively postponed, and often fully prevented, through the application of preventive medicine and modification of the patient's behavioral patterns and environmental factors. The importance of the physician's counsel on ways to prevent disease and avoid accidents has been emphasized.[47] Preventive gerontology is probably one of the most cost-effective services that can be given and encouraged by physicians and other health care professionals.

Although increased appreciation of the importance of preventive medicine is gradually occurring in this country, the American health care system is basically one that waits passively for the individual to seek care. Health professionals should encourage preventive medicine at every opportunity and watch particularly for evidence that elderly persons are at risk and respond aggressively.[48]

Preventive medicine for the elderly has benefited from several trends that have emerged over the past 10 or 15 years. First of all, interest in physical fitness has escalated sharply on a national level. Second, there has been increased interest by health organizations in marketing and consumerism.[49] Older adults are one of the populations most frequently targeted by various organizations for health promotion. The American Hospital Association encouraged their members in 1979 to establish the hospital as an institution in the community that is interested in promoting good health as well as treating disease.[50] Consumers are beginning to view health care as a product for which they can shop around.

Conclusions

Society does not appear to take the challenge of elderly health care seriously enough. Beginning with the education of physicians, nurses, and other health care professionals, students must be made more aware of the large percentage of their careers that will be spent caring for the elderly. They must be sensitized to the needs and feelings of the elderly. Health care workers at all levels should be given the recognition and reimbursement they deserve so that they no longer feel that theirs is a thankless job. Legislators should understand the scope and extent of the problem and appropriate adequate funds. Consumers should be educated so they can carry out their responsibilities pertaining to health care. The task for our society and for organized medicine is a complex and expensive one, but it must be done.

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The Use of Benzodiazepine for Sleep in the Elderly

JIM MONOLAKIS, PHARM.D.

Introduction

SLEEPING disorders are common in people over the age of 65. Sleep patterns change with increasing age and an elderly person is likely to have trouble falling asleep, sleeping lightly, and waking during the night. This usually results in fragmented sleep[1] for which hypnotics are normally prescribed. The elderly account for approximately 11-12% of the American population and receive about 35-40% of the prescriptions for hypnotics. Today, benzopdiazepines are preferred over the earlier hypnotics, such as barbiturates, ethchlorvynol (Placidyl®), glutethamide (Doriden®), antihistamines, and methaqualone (Quaalude®), because of the lower therapeutic to toxic ratio.[3]

However, despite the general claims to safety with benzodiazepines, there has been increasing attention to their adverse effects in the geriatric population because of prescriptions written for the higher strengths. Adverse drug reactions have been reported in less than 3% of persons between the ages of 20-29 years, but as high as 21% in those over 70 years.[1] The higher strength prescriptions of benzodiazepines are associated with an increased incidence of side effects in the elderly, primarily because the pharmacokinetic and pharmacodynamic properties change due to an increase in the ratio of lipid tissue to lean body mass. Most of the benzodiazepines are metabolized by microsomal P-450 oxidation and all are conjugated with glucuronic acid (Figure 1).[3] Agents with long half-lives (Table I) generally have metabolic products of oxidation which retain activity to a greater extent in the elderly.

Pharmacokinetics of Benzodiazepines

Diazepam and chlordiazepoxide have their own activity, as well as the activity of the active metabolite desmethyldiazepam. Clorazepate, prazepam, and to a large extent halazepam rely on desmethyldiazepam for their activity and can actually be thought of as prodrugs.[3] Flurazepam, with its short half-life, is oxidized to three metabolites. Flurazepam aldehyde and 1 hydroxyethyl flurazepam have very short half-lives, whereas desalkyl flurazepam has a longer half-life and contributes to a major portion of the activity of flurazepam. The long half-lives of both desmethyldiazepam and desalkylflurazepam also contribute to drug accumulation.

Drug accumulation with repeated administration is generally related to the dosing frequency and the half-life of the drug or active metabolite. Long half-life benzodiazepines administered nightly will tend to accumulate over a period of three to four weeks, to reach steady state levels in lipid tissue. In contrast, short half-life benzodiazepines, which are less lipid soluble, will have little accumulation, even with repeated night-time administration. Accumulation or unnecessary and excessive use of a benzodiazepine often leads to side effects, such as daytime sedation, confusion, ataxia, and lethargy resulting in falls and fractures in the elderly.

Agents with short half-life (Table 1) do not rely on active metabolites for their duration of effect. Although triazolam and alprozolam are oxidatively metabolized to hydroxy-derivatives, these products are quickly inactivated by glucuronidation and thus the duration of action is regulated by the half-life of the parent compound. Temazepam, lorazepam, and oxazepam are inactivated by direct conjugation with glucuronic acid. Since conjugation does not appear to be affected by aging, the half-life of these three drugs tend to be the same in the elderly as they are in young adults.[3]

Prescribing Recommendations In the Elderly

In spite of some claims to the contrary, all of the benzodiazepines are qualitatively similar in their pharmacologic action, and whether a given benzodiazpine is promoted as an anxiolytic, muscle relaxant, or a sedative/hypnotic is sometimes based primarily on the marketing

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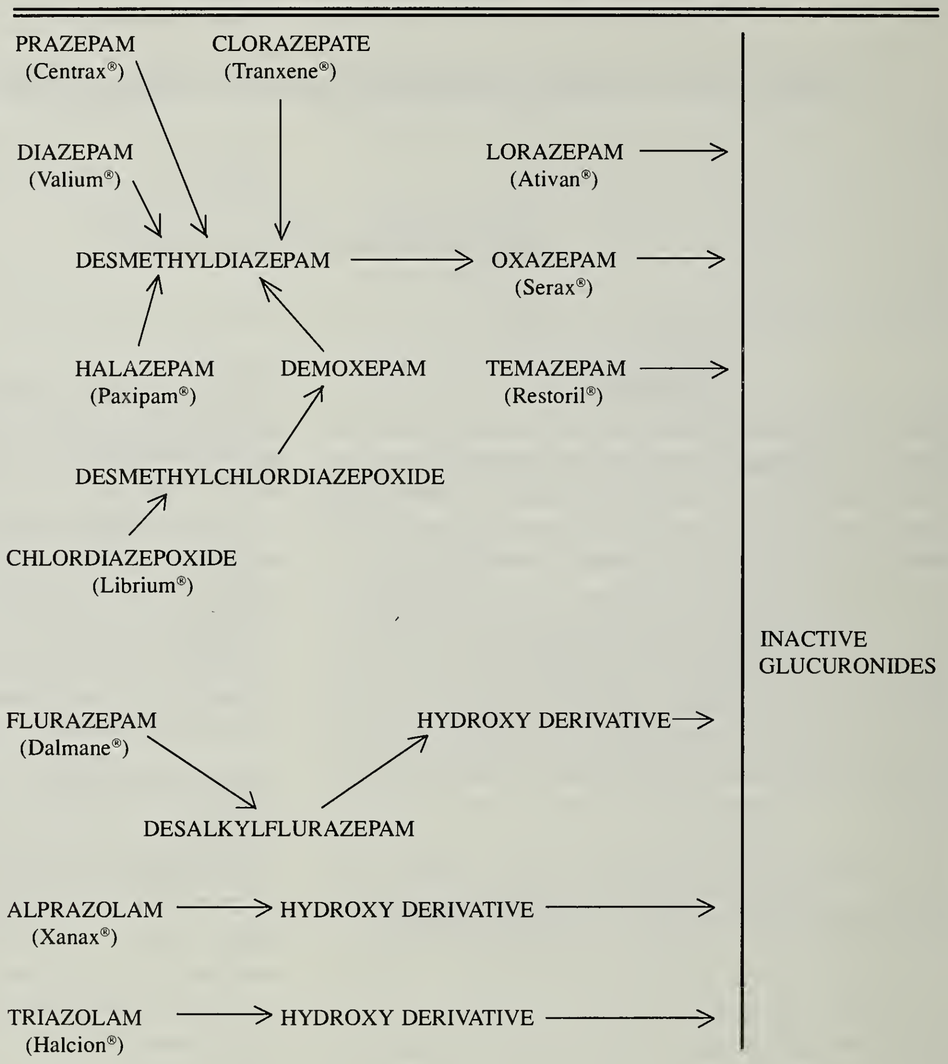
Editors: Moses Sing Sum Chow, Pharm. D., and Robert A. Quercia, M.S., R.Ph.

strategy rather than on any real differences among the drugs.[3] Because the elderly are generally pharmacokinetically different from the younger adult group, it would be rational to prescribe a benzodiazpine with a short half-life. Triazolam is good for those patients who only have difficulty falling asleep. For those who have sleep continuity disturbances during the second half of the night, which is the most common sleep complaint of geriatric patients, triazolam is likely to be less effective. Hypnotics with slightly longer half-lives, such as temazepam, lorazepam, and oxa-zepam, should be preferred agents in the elderly and are best given one to two hours before bedtime. Of the long half-life benzodiazepines, flurazepam, is the most commonly prescribed for sleep.[2] However, it is a poor choice for use in the elderly individual who requires more than the occasional use of a hypnotic agent because of accumulation of active metabolites resulting in increased side effects. The lowest effective dose (Table 1) and shortest duration of therapy with a short half-life benzodiazepine (ie, temazepam, oxazepam, lorazepam, and triazolam) should be preferred over longer-acting benzodiazepines to avoid any unneccessary side effects.

Figure I[3]
Metabolic Pathways of Commonly Used Benzodiazepines



Nonpharmacologic methods should be encouraged during hypnotic therapy to decrease the duration of therapy and increase its effectiveness. These include: 1) trying to wake up and go to bed at about the same time each day, 2) avoiding naps as much as possible, 3) not going to bed early to catch up on lost sleep, 4) avoiding a large meal before bedtime, but a snack may help, 5) avoiding excessive alcohol, caffeine, or nicotine for at least several hours before sleep, and 6) engaging in pleasant or relaxing activities one to two hours before going to sleep.[3]

Also, vigilance should be used when prescribing a benzodiazepine with other sedating agents such as tricyclic antidepressant agents, phenothiazines, narcotic analgesics, daytime benzodiazepines, and especially alcohol.

Summary

When benzodiazepines are used for sleep in the elderly, it is important to prescribe the lowest effective dose and those agents with short half-lives (ie, triazolam, temazepam, lorazepam, and oxazepam) to avoid an increase in the incidence of adverse drug reactions. Also, it is important to maximize hypnotic therapy by encouraging nonpharmacologic methods of sleep.

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Table I[3,4]

Name	Primary FDA-approved use	Onset of action after oral admin	Half-life of drug as active metabolite (hr)	Usual dose for the elderly (mg/hs)	Cost of daily dose (dollars)[1]
Generic (Trade)					
Long half-life					
Chlordiazepoxide (Librium)	Anxiolytic	1 hour	>100	5	$0.18
Clorazepate (Tranxene)	Anxiolytic	30 minutes	>100	7.5	$0.53
Diazepam (Valium)	Anxiolytic	15 minutes	>100	2	$0.21
Flurazepam (Dalmane)	Sedative/hypnotic	30 min-1 hour	>100	15	$0.29
Prazepam (Centrax)	Anxiolytic	2 hours	>100	10	$0.41
Halazepam (Paxipam)	Anxiolytic	2 hours	>100	20-40	$0.26-$0.36
Short half-life					
Alprazolam (Xanax)	Anxiolytic	1-2 hours	12-15	0.25-1.0	$0.30-$0.54
Lorazepam (Ativan)	Anxiolytic	1-2 hours	10-20	0.5-2.0	$0.30-$0.61
Oxazepam (Serax)	Anxiolytic	2 hours	5-14	10	$0.32
Temazepam (Restoril)	Sedative/hypnotic	1-2 hours	10-20	15	$0.31
Triazolam (Halcion)	Sedative/hypnotic	30 min-1 hour	1.5-5	0.125-0.25	$0.34-$0.37

[1] Average wholesale price

CMIC Waives Premium for M.D.'s on Active Duty

Glastonbury, CT (December 4, 1990) — Connecticut physicians among the reservists called to active duty for Operation Desert Shield insured by Connecticut Medical Insurance Company are getting a break.

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CMIC's prompt response to the first call-up of medical reserves in August was recognized by the office of the Surgeon General of the Navy. In a letter to CMIC, Vice Admiral of Medical Corps James A. Zimble stated: "You have materially contributed to the morale of our uniformed providers by removing a serious financial risk. Your actions help make it possible for America to assure those 'in harm's way' quick, appropriate healthcare services if wounded, injured or fallen ill during their arduous deployments around the world." Vice Admiral Zimble adds, "You have helped set the standard of support for other Americans to see and follow."

CMIC, physician-owned and operated, was established in 1984 by the Connecticut State Medical Society and provides medical malpractice insurance for 2,600 physicians. Within six years, CMIC has become the largest insurer of Connecticut physicians.

HELPFUL HINTS

Prep / Drape

E. TREMAIN BRADLEY, M.D.

WHEN it comes to getting a patient ready for surgery in the operating room, there are five details that I find worth mentioning.

First is the application of antiseptic to the skin. (The choice of what to use varies with the current popularity, almost like a fad.) I like to start "painting" at the incision site, continuing in an outward spiral, never coming back toward the center with the same "paint brush." Of course, we have to admit that none of this leaves the skin really bacteria-free. The body's resistance is to be thanked for helping keep the incidence of wound infection so low.

Second: After the operative area has been outlined with drapes, we then open all additional large drapes over the sterile drapes already in place.

Third: Use of a suction tube is often anticipated. It can conveniently be pinched to the ether screen through the drapes using an Allis clamp.

Fourth: In preparing a male in lithotomy position, the genitalia can be lifted away from the perineum—and kept away—by using a wet towel partly wrung out. This is placed under the scrotum and the ends extended taught out into the groins.

Fifth: Again for lithotomy where separate leg drapes are used, I have found that starting with a double cuff, utilizing each cuff in succession, makes the application less awkward and tends to avoid the risk of contamination.

E. TREMAIN BRADLEY, M.D., solo practice of General Surgery, retired to Norfolk.

Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed $1^{1}/_{2}$ pages of text (excluding references). They should not duplicate similiar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

HYDROXYCHLOROQUIN AND CHRONIC SINUSITIS

To the Editor: I would like to report a case where hydroxychloroquine therapy, 200 mg b.i.d., being given for rheumatoid arthritis caused a significant and sustained improvement in the patient's chronic sinusitis. The latter had been manifest as chronic (four-year history) pain and tenderness over the areas of the maxillary sinus, and to a lesser extent the frontal ones. There had been for years a small amount of pale yellow postnasal drainage constantly. X-ray films of the paranasal sinuses showed no mucosal thickening or air fluid levels. Two ENT physicians had advised septal surgery for a deviated septum and one had suggested nasal steroids. Neither form of treatment was adopted. Although some small benefit, ie, decrease in nasal stuffiness, was noted transiently even with the first tablet, maximum benefits were not achieved until about five to six months (about the same time the patient got some benefit from his symptoms of rheumatoid arthritis). Although some nasal stuffiness and clear postnasal drip remain, there is no longer any purulent drainage; sinus pain and tenderness have virtually completely disappeared and the patient no longer uses any antihistamines or decongestants at all.

It is possible that the hydroxychloroquine's interference with the production, by monocytes, of interleukin 1, a mediator of inflammatory response and one whose suppression has been suggested to cause improvement in rheumatoid arthritis, was the cause of the marked beneficial effects of the drug.[1]

James J. Purcell, M.D.

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Pegademase

THE MEDICAL LETTER

PEGADEMASE (*Adagen*-Enzon), bovine adenosine deaminase (ADA) conjugated with polyethylene glycol (PEG), was recently approved by the US Food and Drug Administration as an "orphan drug" for treatment of severe combined immunodeficiency disease (SCID). SCID due to inherited deficiency of ADA occurs in less than one per million births; until recently, without extraordinary isolation measures, it was usually fatal before the age of two.

MECHANISM OF ACTION — ADA is a cytoplasmic enzyme with greatest activity in lymphoid cells. In the absence of the enzyme, adenosine, deoxyadenosine, and their metabolites, which are toxic to lymphocytes, accumulate and cause lymphopenia and susceptibility to recurrent infections. Given alone, the enzyme is eliminated too rapidly to be helpful, but covalent attachment of PEG, a hydrophilic inert polymer, slows elimination while preserving catalytic function. Pegademase provides prolonged circulating ADA activity, leading to efficient extracellular elimination of adenosine and deoxyadenosine, reversing toxic metabolic abnormalities in ADA-deficient cells, and improving immune function.

OTHER TREATMENT — The most effective therapy previously available for SCID has been HLA-matched bone marrow transplantation, which offers a potential cure. HLA-haploidentical bone marrow transplantation has been less successful (J Barrett and D McCarthy, Blood Rev, 4:116, June 1990). Inserting the ADA gene into the patient's lymphocytes is now under consideration (BJ Culliton, Science, 249:975, Aug 31, 1990).

PHARMACOKINETICS — After IM injection of pegademase, plasma ADA activity peaks within 48 to 72 hours, with a half-life ranging from three to more than six days.

CLINICAL TRIALS — In 14 children treated with pegademase, 12 for one to more than four years, responses have been similar to initial results in three of the patients (MS Hershfield et al, N Engl J Med, 316:589, 1987; Y Levy et al, J Pediatr, 113:312, 1988). T-lymphocyte counts increased in all patients, beginning a few weeks to six months after starting treatment. The majority have recovered specific immune responses; in a few, reconstitution has been slower and less complete. All patients have shown clinical improvement indicated by normal frequency of and recovery from ordinary childhood infections and fewer opportunistic or life-threatening infections. Pegademase does not cure SCID, however, and must be given for life; its long-term effectiveness is unknown.

DOSAGE AND COST — ADA levels are measured to determine the dosage and schedule of administration for each patient. The usual maintenance dosage is 20 units/kg IM once a week, but some patients have been given up to 30 units/kg twice a week. The cost of one year's treatment for a small child is about $60,000.

ADVERSE EFFECTS — Except for discomfort at the injection site in some patients, no toxic, allergic, or other adverse effects have been reported. Antibodies to ADA have become detectable in most patients, but generally without any effect on the pharmacokinetics or effectiveness of the drug.

CONCLUSION — Severe combined immunodeficiency disease (SCID) due to adenosine deaminase deficiency can now be treated effectively with intramuscular injections of pegademase, a conjugated formulation of the missing enzyme.

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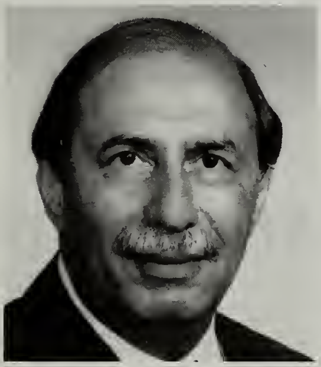

By the time you read this, you may have already received a new informational packet containing eight colorful 1991 health promotion pamphlets. They have just been published by CSMS as a public health service for your patients. We sent an advance mailing to you, so that you may be the first to read them, to encourage your office staff to read them, and to consider ordering more for your waiting room, or for those patients you think might profit by them.

You will notice that among the health promotion titles relating to smoking, alcohol, STD's and diet, there are also some titles relating to patient-physician relationships and health care costs. These are written from the physician's point of view, a perspective that the public rarely or never hears, particularly not from the news media or from governmental representatives.

Life-style abuses do cause much of the illness whose costs physicians often get blamed for, but there are other costly factors, too, like third-party administrative costs, litigiousness, the "hassle factors" associated with "managed care," and cost-shifting. These divert an ever-growing share of the health care dollar to unproductive paper-shuffling, which cures no ills and saves no lives.

Reasonable numbers of these new CSMS pamphlets are available to you without cost as packets of eight, the format in which you received them, or separately by title. Pass them on to selected patients, or to local opinion leaders in your community known to you. There is room on the back of the pamphlets and of the packet for your own personal sticker or rubber stamp. You may also order the Spanish-language version of the pamphlets, now in preparation, which will also be available from CSMS.

Part of our 1991 Health Promotion Project will be to supply these packets also to legislators and other government leaders, public health agencies, schools, libraries, employers, unions, news media and service agencies. Also, watch for a series of newspaper ads being planned to offer the new pamphlets to responding members of the general public.

And finally, don't hesitate to send us your own suggestions for effective distribution of these "physician-friendly" health promotion guides. To borrow a quote from a popular article from *Private Practice* authored by Tim Norbeck, our CSMS Executive Director, "The truth requires constant repetition, because error is being preached about us all the time." (Goethe)

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REFLECTIONS ON MEDICINE

Counsels of Restraint

ROBERT U. MASSEY, M.D.

EACH fall medical school faculty members, department heads, teaching hospital directors, and deans gather together to talk about medical education and research, especially medical school and teaching hospital finances and the federal government's support for biomedical research. It is a big meeting; this year's event in San Francisco, the 101st Annual Meeting of the Association of American Medical Colleges (AAMC), drew 3,500 participants. Although during the first half of its life the AAMC was regarded by many as a dean's club—I recall the director of a teaching hospital telling me 25 years ago that "they had really weird theories about medical education,"—this organization has been of substantial importance in the evolution of medical education in North America.

Reorganized from the defunct American Medical College Association in 1890, the AAMC emerged at the height of the reform movement in medical education.[1] Its leadership position and the influence of academic physicians on American medicine grew steadily, reaching their zenith during the "Golden Era" of the NIH and of scientific research generally, following the launching of Sputnik in 1957. In 1960 there were 86 medical schools, the same number as in 1920; 20 years later there were 127 schools, and the number of entering students had more than doubled. In recent years growth in research funding has slowed, and may even be declining; student numbers have leveled off, and have even declined modestly in some schools. In his chairman's address this year, David H. Cohen, vice president for research and dean of the graduate school at Northwestern University, urged "fiscal restraint":

"As we move into the 1990s I believe we must reevaluate the extent to which our traditional base of public support prevails as other issues capture increasing public concern and as negativity about uncontrolled health care costs grows." Reminding his audience of these "other issues," the environment, the crisis in education, drugs, the savings and loan bailout, and the possibility of war in the Persian Gulf, he observed that not everyone, not even other scientists, may see biomedical research as the number one priority. There is a "need for setting priorities," he said, "and a willingness to engage that exercise with a sense of compromise and responsibility. . . ."

He hoped that the scientific community could do this, could self-regulate, and would seek to work within a predictable base budget that would increase with inflation, and a discretionary budget that would reflect national needs and available resources. Those of us who have attempted to engage faculty members and departments in our own institutions to do just that were not sanguine. But this may be the first time that we who have been attending AAMC meetings for years have heard such cautionary remarks and counsels of restraint. The hundredth anniversary may indeed mark the closing of an era of exuberant growth.

In a similar vein, AAMC president, Robert G. Petersdorf, noted the inexorable increase in the costs of medical education, with tuition in private medical schools ranging from $8,650 to $24,300, and in public schools from zero to $9,956; to this must be added living costs of over $10,000. Student indebtedness continues to climb faster (almost twice as fast in most recent years) than the rate of inflation. At the University of Connecticut School of Medicine, where tuition and fees total $7,800, average medical education indebtedness is $36,500, ranging up to $65,300. Such amounts could mean monthly payments of over $1,000 for 20 years; surely this must affect career choices, although until now the data have been unclear. Dr. Petersdorf urged, in addition to debt counseling and debt limits for students, restraint by medical schools in raising tuition. Restraint here would mean limiting budgets, limiting staff and faculty size, limiting building, and the thoughtful setting of priorities.

"The No-Growth Society" was the theme for the fall 1973 issue of *Daedalus* at a time when zero population growth was taken seriously. Following the first oil crisis it was understandable that zero economic growth should be examined as well. Dr. Cohen commented in his presidential address this year that "the noble and good cannot always prevail; we live in an imperfect world." In the past two decades we have received two clear reminders: ours also is a world of unforgiving limits.

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LAW, MEDICINE AND PUBLIC POLICY

Nancy Cruzan and the U.S. Constitution: Justice Brennan's Farewell

JOSEPH M. HEALEY, J.D.

THE majority opinion in the Cruzan case,[1] authored by Chief Justice Rehnquist, concluded that even if it were assumed that a patient had a constitutionally protected right to refuse treatment (including artificial nutrition and hydration), a state might still impose evidentiary standards which limit the exercise of that right. Using this conclusion as a base, the majority opinion upheld the Missouri Supreme Court's judgment that clear and convincing evidence of the incompetent patient's wishes must be obtained and that this standard had not been satisfied in the Cruzan case. In contrast, the separate dissenting opinions of Justice Brennan and Justice Stevens[1(pp 4926-41)] concluded that there is a constitutionally protected, fundamental right of a patient to be free from unwanted medical treatment; that the state's interest in protecting and preserving life does not justify requiring Ms. Cruzan to continue to receive unwanted medical treatment; and that the State of Missouri had placed impermissible barriers to the exercise of Ms. Cruzan's constitutionally protected rights. Justice Brennan's eloquent dissent deserves special attention because it is among his last written opinions before his retirement from the Court and it highlights his concerns about the state of American constitutional law in the health law context.

Justice Brennan, using concepts borrowed from a previous opinion of an Arizona Court, describes Ms. Cruzan as a dweller in that twilight zone "where death commences while life, in some form, continues."[1(p4926)]She is permanently and irreversibly unconscious. Her previous expressions indicate that she would not wish continuation of her treatment. Her family and friends are convinced that she would wish discontinuation. An independent guardian concluded that she would not want treatment to continue. Nonetheless, the majority of the Missouri Supreme Court and of the United States Supreme Court would not permit this discontinuation.

In contrast to the chief justice, Justice Brennan believes that Ms. Cruzan clearly possesses a fundamental right to be free from unwanted medical treatment including artificial nutrition and hydration which is not outweighed by any state interests. This right is grounded in the larger right of self-determination which permits an adult person of sound mind to make decisions for herself. When a patient is incompetent, the state has an interest in assuring that as accurate a determination as possible be made of the patient's wishes. However, the state has no legitimate general interest in a patient's life "completely abstracted from the interests of the person living that life." Justice Brennan objects to what he describes as "improperly biased procedural obstacles imposed upon Ms. Cruzan"[1(p 4926)] For example, he noted the asymmetrical burden of evidence reflected in the high standard of certainty which the state requires for treatment refusal, while requiring no proof of the patient's wishes to continue treatment. Justice Brennan rejected the claim that the heightened evidentiary standard is necessary to advance the state's interest in protecting and preserving life. He also disapproved of the categorical exclusion or ignoring of evidence from her family, friends, or court-appointed guardian tending to prove that Ms. Cruzan would wish discontinuation of treatment. While the choice of a mechanism to assure that the patient's wishes are known and followed should generally be left to the individual states, such a mechanism should not employ prejudicial procedures, nor allow the state to usurp the authority of patient, family member, or surrogate decision maker. Brennan argued:

> A State may ensure that the person who makes the decision on the patient's behalf is the one whom the patient himself would have selected to make that choice for him. And a State may exclude from consideration anyone having improper motives. But a State generally must either repose the choice with the person whom the patient himself would most likely have chosen as proxy or leave the decision to the patient's family.[1(p4933)]

While recognizing the dangers of undertreatment, of

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

those circumstances in which a patient might be denied beneficial treatment by improperly motivated caregivers or surrogates, Brennan also recognizes the dangers of overtreatment, of those circumstances in which a patient is compelled to receive nonbeneficial treatment for equally improper reasons. Out of his analysis emerge three circumstances in which there is a responsible role for the state: (1) when there is reasonable doubt about the patient's condition and likelihood of recovery; (2) when there is reasonable doubt about the patient's wishes; (3) when there is reasonable doubt about the surrogate decision maker's exercise of the patient's rights. Based on his reading of the facts in this case, Justice Brennan found none of these sufficiently present to justify denying Ms. Cruzan's parents' request to implement their daughter's wishes.

Discussion of the case will continue next month.

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1. *Cruzan v. Director, Missouri Dept. of Health, et al,* 58 LW 4916 (1990).

M.D. HEALTH PLAN UPDATE

M.D. Health Plan is the CSMS-sponsored statewide HMO which is wholly owned and directed by practicing physicians. Barely three years in operation, total M.D. Health Plan membership is nearing 50,000 as of December 1990, from over 1,900 employer groups. CSMS-IPA physician participation has increased by 425 this year, making a total of 2,700 physicians in over 4,400 medical office sites throughout the state.

CSMS-IPA Membership Fee to Rise

Effective February 1, 1991, the CSMS-IPA Board has authorized an increase in the one-time membership fee for participation. For family physicians, pediatricians, and general internists, the fee will be increased from $250 to $500. For specialists, the fee will be increased from $500 to $750. Those considering joining in 1991 have only the month of January to do so at the old rates.

Revenues, Profits Up

M.D. Health Plan's third quarter results showed a profit surplus of $1,207,122 on revenues in excess of $15 million for the period. This marks MD's seventh consecutive profitable quarter and shows it 7% ahead of projected revenue and 5% ahead of projected enrollment. At the recent fall meeting of the CSMS House of Delegates, it was announced that this favorable performance had permitted M.D. Health Plan to pay off a $600,000 bank line of credit earlier than expected, thus releasing CSMS as guarantor. CSMS had undertaken that role in 1988, to assure M.D. Health Plan's success and stability at a critical point in its early development. Speaking for the MDHP board, Chairman Vincent Catrini, M.D., thanked the CSMS House of Delegates for the Society's vision, confidence and support during those crucial first years.

MDHP Concludes Employer Survey

M.D. Health Plan has recently concluded an independent, statewide survey among the benefits administrators of participating employers. Conducted by JHH Market Directions of Avon, the survey was designed to determine the levels of satisfaction among these client constituents concerning price, quality and service; MD's two new product offerings—its open-ended and self-funded programs; plus its image vis-a-vis HMO and indemnity carrier competitors.

The consensus among the benefits administrators clearly showed that competitive premium costs, statewide physician access, and statewide hospital coverage were the three major features that persuaded their companies to offer M.D. Health Plan to their employees. The administrators agreed that the Plan served their employees well, which in turn resulted in overall good service to the employer organization.

—ROBERT J. BRUNELL, Director of Scientific Affairs, Connecticut State Medical Society.

50 Years Ago

From the *Journal of the Connecticut State Medical Society*

December 1940

Get Off the Cracker Barrel!

NOW that the smoke from the presidential contest has cleared away and with it have vanished traces of some of the emotional crudities of our democracy, we may well contemplate what the future holds for the practice of medicine in this country. The defeatist attitude is all too prevalent. Rumblings of the threat of dictatorship and of the downfall of our democracy, be they fact or fancy, cannot be denied. To the careful student of trends and developments in the United States during the past ten years the presidential election of 1940 is no surprise. Living as we do in the midst of these social and economic changes it is difficult for most of us to get the proper perspective and realize that actually a social and economic evolution is taking place about us. Some of our professional friends have been heard to express themselves as confident that there is nothing in the future practice of medicine which should appeal to their sons as they become eligible.

There is no surer way to strike a fatal blow at democracy and at those principles which are undergoing the test than this attitude of defeatism. Dictatorship in the United States can never materialize unless public opinion becomes throttled. Never has the practice of medicine offered more varied fields of opportunities to a young man than it does today. We have been told in a recent address by our President that there will be no socialized medicine in this country, that government and profession are uniting in efforts to improve medical care. Few seem to realize that many of the principles of socialized medicine already exist and, whether we like them or not, they must be, jealously guarded by the medical profession or surrendered to government control. This alone should challenge us.

With enforcement of the Selective Service Act, with the postponement, for the present at least, of prosecution of the federal suit against organized medicine, and with the appointment by our President of the Health and Medical Committee of the Council of National Defense, the picture is not as black as some would like to have us believe. The profession is receiving an unprecedented recognition in the operation of the Selective Service Act. Advice has been freely sought at Washington from organized medicine and the voice of the profession is becoming more authoritative in the halls of our present administrative bodies. Should a future attempt be made to thrust upon our people compulsory health insurance, as some still predict, we shall have secured a tenable position at Washington which may bring about closer cooperation between the government and the medical profession. The postponement of the federal suit against organized medicine may have been but a diplomatic move but as such will develop to our own advantage. Whatever way we turn deep and far reaching changes are taking place in our democratic mode of living. Naturally the practice of medicine is not immune. The opportunities for leadership afforded our profession have presented themselves so rapidly that it is with difficulty that we keep our field of vision clear and our processes of thinking unclouded by the inconsequential and irrelevant; but this must be done.

—Editorial from *The Connecticut State Medical Journal*, December, 1940.

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a free service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to Physician Placement Service, Connecticut State Medical Society, 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

FAMILY PRACTICE

Four doctor family practice group seeks board certified/board eligible F.P. to join them in May 1991 (or soon after). Busy office and hospital practice including ICU, CCU, Pediatric, and Nursery privileges. (No O.B.) Shoreline community with excellent schools and quality of life. Favorable call schedule. Both full-time and part-time considered. Send CV to : Dr. Steven W. Luger, 8 Davis Rd., Old Lyme, CT 06371 or call (203) 434-8300.

FAMILY PRACTICE/INTERNAL MEDICINE

FP/INTERNIST—BE/BC sought for Southern Fairfield County Community. Opportunity to share established group practice. Salary/benefit package, including malpractice. Start 1991. Send letter of interest and CV to: CSMS, c/o FP/KO.

INTERNAL MEDICINE

BC/BE internist to replace retired physician. Opportunity to build own practice; share office, expenses, and coverage. Please send CV to George Burton, M.D., 488 Montauk Ave., New London, CT 06320.

Internist, with or without subspecialty, to associate with internist/cardiologist. Open both to established practitioners and those fresh from residency or fellowship. Begin anytime up to July, 1991. Send CV to Jonathan Greenwald, M.D., FACP, FACC, 148 East Ave., Norwalk, CT 06851-5734; Tel: (203)866-7000.

Small private practice in Greater Hartford area looking for internist. BC/BE. Salary plus bonus and partnership potential. Affiliated with local hospital. Great growth potential. Available immediately. Call (203)676-0680 or send CV to : Devra Sisitsky, Suite 103, 302 West Main St., Avon, CT 06001.

Internist. BE/BC. Southeastern Connecticut. Excellent hospital, good schools, and supportive hospital administration. Excellent coverage. Busy office, hospital and nursing home. Write, Edward J. McDermott, M.D., 174 Bridge St., Groton, CT 06340.

Internal medicine physician to join busy solo practice in Central Connecticut. Reply to: 245 North Main St., Wallingford, CT 06492.

PART-TIME

Part-time physician needed. Position available immediately. Evenings (4:00-8:00) and some Saturdays (9:00-5:00). Please call (203)665-0305, any weekday between 9:00 and 4:00.

PEDIATRICS

Connecticut—BC/BE pediatrician needed to join two young pediatricians in rapidly growing central Connecticut practice. Send CV to: Mitchel Katz, M.D., 760 Saybrook Rd., Middletown, CT 06457.

Pediatrician full or part-time to replace physician in four doctor group. Affiliated with teaching hospital with residency program. Also associated with University Health Service. Please contact: Francis J. Scholan, M.D., 99 Harbor Rd., Southport, CT 06490.

Coastal Connecticut. BC/BE pediatrician to join busy two-person practice in beautiful shoreline community. University affiliated hospital nearby. Excellent salary, production bonus, early partnership. Available July 1991. Send CV to CSMS, c/o, PED/PY.

Exceptional opportunity to join a pediatric group practice of four BC/BE pediatricians. Practice is located in shoreline community five miles from Yale-New Haven Medical Center, our chief hospital affiliation. Sole owner is original partner of practice established in 1955. Starting salary $80,000.00 per year with buy-in option after one year. Part-time position also available. Call (203) 248-4846 any evening after 8:00 P.M.

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Primary Care—Internist—New position, immediate opening to join Yale affiliated comprehensive health center. Yale admitting privilege and clinical faculty appointment; teaching and research roles possible. Very competitive salary. Decent on-call—one weeknight/week and one weekend/5 weeks. Five weeks vacation and personal time; one week CME. Join a young collegiate group of four physicians and two PAs. Send CV to Stephen Updegrove, M.D., Medical Director, Hill Health Corporation, 428 Columbus Ave., New Haven, CT 06519. (203) 776-9594; FAX (203) 787-5510. EOE M/F.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

FAMILY PRACTICE

July '91. No age given. FLEX. AB elig. MD, University Health Sciences, Kansas City Osteopathic School, Kansas City, MO; Int. and Res., University of Massachusetts Medical Center, Worcester, MA. Very interested in *Obstetrics*. Prefers solo, group or associate type practice in small-sized community in the southwestern part of Connecticut. Write Gwen Broz, D.O., 18 Harlow St., Worcester, MA 01605.

Oct. '90. Age 34. Presently in practice. Nat'l bds. AB cert. M.D., Medical College of VA; Int. and Res., Abington Hospital, Abinton, PA. Prefers group, associate or institutional type practice. Write, Jeffrey C. Ettinger, M.D., 501 Bryce Canyon Court, Petaluma, CA 94954.

FAMILY PRACTICE/GENERAL SURGERY

PART TIME. Immediately available. Age 76. Licensed in Connecticut. Nat'l bds. AB cert. MD, SUNY, Syracuse, NY. Int., Brooklyn Hospital, Brooklyn, NY; Res., Mount Sinai Hospital, New York, NY (formerly NY Post-Graduate Hospital). Prefers group, associate or institutional type practice (24-32 hrs/wk). Write, CSMS c/o MM/FP.

INTERNAL MEDICINE

Jan. '91. Age 37. Presently in practice. Nat'l bds. AB elig. MD, Columbia University College of Physicians and Surgeons, New York, NY; Int. and Res., North Shore University Hospital, New York, NY. Prefers group type practice in a medium-sized community. Write, CSMS c/o JJ/IM.

Immediately available. *Cardiology*. Age 30. Presently in practice. Nat'l bds. AB cert. MD, New York University, New York, NY; Int., Res., and Fellowship, Dartmouth, Hanover, NH. Prefers solo or group type practice in a medium-sized community. Write, Daniel G. Dadourian, M.D., 14 Maple Terrace, West Roxbury, MA 02132.

July 1991. Age 29. AB elig. MD, Albany Medical College, Albany, NY; Int. and Res., Albany Medical Center, Albany, NY. Prefers group or associate type practice in a medium-sized community. Write, James Scarles, M.D., 1032 Washington Ave., Albany, NY 12203.

Availability pending. Age 33. Nat'l bds. AB cert. MD, New York University, New York, NY; Int. and Res., Thomas Jefferson University, Philadelphia, PA. Prefers group, associate or institutional type practice particularly affiliated with a teaching hospital. Write, Joanne C. Reisch, M.D., 10 Monroe Dr., White Plains, NY 10605.

OPHTHALMOLOGY

Immediately available. Age 47. Licensed in Connecticut. AB cert. MD, University of Tennessee, Memphis, TN; Int., Baptist Memorial Hospital, Memphis; Res., Brooke Army Medical Center, San Antonio, TX. Solo practice, New Haven, 1976-1989. Prefers full or part-time employment with group or solo; medical ophthalmology and/or anterior segment surgery. Write, Jeffrey D. Gold, M.D., 91 Curtis Dr., New Haven, CT 06515.

ORTHOPEDICS

Jul. '91. Age 32. MD, New York Medical College, Valhalla, NY; Int. and Res., St. Lukes/Roosevelt Hospital, New York, NY; Fellowship, Hospital for Joint Diseases, New York, NY. Prefers solo or associate type practice in a small to medium-sized community. Write, James T. Mazzara, M.D., 68-15 Selfridge St., #2C, Forest Hills, NY 11375.

PLASTIC SURGERY

Dec. '90. Age 40. Licensed in Connecticut. FLEX. AB cert. Autonoma University of Guadalajara, Jalisco, Mexico; Int., Maryland General Hospital, Baltimore, MD; Res., New Britain General Hospital, New Britain, CT; Fellowship, Saint Barnabas Hospital and Medical Center, Livingston, NJ and the University of Connecticut Health Center, Farmington, CT. Prefers institutional or industrial type practice. Write, Nicholas Mikula, Jr., M.D., 12 Clapboard Ridge Rd., Apt. 12-H, Danbury, CT 06811.

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All paid classified advertising orders, correspondence and payments should be directed to : CONNECTICUT MEDICINE, Classified Department, 160 St. Ronan St., New Haven, CT 06511, Tel. (203) 865-0587. The classified rates are as follows: $60.00 for 25 words or less; plus $1.00 for each additional word. For confidential answers, the cost is $3.00 per insertion, sent in care of CONNECTICUT MEDICINE. Ad copy, with payment, must be received no later than the first day of the month preceding month of issue.

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